EXHIBIT B

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875
THIS DOCUMENT RELATES TO ALL CASES	

CONFIDENTIAL INFORMATION - SUBJECT TO PROTECTIVE ORDER

VIDEO DEPOSITION OF DANIEL CATENACCI, M.D.

VIA VIDEOCONFERENCE

September 13, 2021

9:20 a.m.

Volume 1

Reporter: John Arndt, CSR, CCR, RDR, CRR
CSR No. 084-004605
CCR No. 1186

DEPOSITION OF DANIEL CATENACCI, M.D., produced, sworn, and examined via videoconference on September 13, 2021, in the City of Chicago, State of Illinois, before John Arndt, a Certified Shorthand Reporter and Certified Court Reporter.

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Michael Newell (videographer)

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THE VIDEOGRAPHER: We are now on the record. My name is Michael Newell. I'm a videographer for Golkow Litigation Services. Today's date is September 13, 2021. The time is 9:20 AM. This remote video deposition is being held in the matter of in re Valsartan, Losartan, and Irbesartan products liability litigation for the U.S. District Court, District of New Jersey. The deponent today is Daniel Catenacci, M.D.

All parties to this deposition are appearing remotely and have agreed to the witness being sworn in remotely.

Due to the nature of remote reporting, please pause briefly before speaking to ensure all parties are heard completely.

Will counsel please identify themselves for the record?

MR. SLATER: Adam Slater for the plaintiffs.

MR. INSOGNA: Nick Insogna, Greenberg Traurig, for the defendants. Also in the room with me are Clem Trischler for defendants and Kate Wittlake for defendants, and also Scott Morgan for plaintiffs.

MR. SLATER: Okay.

THE VIDEOGRAPHER: Okay. The court

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reporter today is John Arndt and will now swear in the witness

The witness, DANIEL CATENACCI, M.D., first having been duly sworn, testified as follows:

EXAMINATION

BY MR. SLATER:

Q. Good morning, Dr. Catenacci.

A. Good morning.

Q. I'm Adam Slater. I'm going to take your deposition now in this litigation. You understand that's the purpose of this proceeding; correct?

A. Yes.

Q. You understand you must tell the truth in response to every question I ask you?

A. Yes.

Q. If I ask you a question that for some reason is unclear to you or for any reason you don't think you can answer it truthfully and completely because of some question about what I'm asking, just tell me. You can tell me the question's not clear. We can specify what it is and I'll try to reask the question if necessary. Okay?

A. Okay.

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Q. Attorneys may object during the course of the deposition. I think you've been through some, but I'll just let you know or remind you that lawyers are allowed to object. They're preserving their right for the future.

It's never, ever supposed to be a signal to you for how to answer, so I would assume that's not going to be happening, obviously, but don't be thrown off by objections or discussions by counsel. And I would assume, unless there's a very, very narrow exception, you will be told to go ahead and answer the question after an objection is placed. Okay?

A. Okay.

Q. Did you prepare for this deposition?

A. Yes.

Q. When did you first start preparing for the deposition?

A. Essentially I guess I started preparing when I started reading about the topic in general. But certainly after my report I knew that there was going to be a deposition that would have told me which -- we were deciding on which date. So during that time I continued my reading. I was always reading and continuing to get a broader understanding of the topic.

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Q. You referred to the point in time when you started reading about the topic in general. When was that?

A. It was after I was contacted to serve as an expert on the case.

Q. Am I correct in understanding that before you were first contacted to potentially act as an expert for the defense in this case, you were not reading up on the issues that are specific to this report that you've written?

A. That's correct.

Q. And for example, you weren't following the issue of nitrosamines in valsartan before you were contacted?

A. I heard of it. I heard of other stories along that line, but I didn't focus on this in any in-depth manner.

Q. Let's put up -- well, rephrase. Let's identify for the record Exhibit 1, which will be the notice to take deposition.

[Exhibit 1 marked for identification.]

BY MR. SLATER:

Q. And I don't know if you have that in the room. If you do, we don't have to put it on the screen.

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MR. INSOGNA: If you could put it on the screen, that would be helpful.

MR. SLATER: Okay. Go ahead, Chris.

BY MR. SLATER:

Q. Doctor, Exhibit 1 is the notice to take your deposition. Have you seen that document before?

A. Yes.

Q. Did you read the entire notice?

A. Not in great detail.

Q. Well, did you read the notice? Did you read each of the categories of document requests?

A. Yeah, I looked through the -- I looked through it, yes.

Q. Did you make any effort to locate and produce any of the documents requested in the deposition notice?

A. I did not do that myself.

Q. With regard to documents that would have been in your possession and control, as opposed to something that the lawyers who retained you might have, did you make any effort to look for those documents that were requested?

MR. INSOGNA: Object to form.

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A. I didn't need to because I had looked at the documents that were produced that was comprehensive for my whole report and all of my reliance list -- all the documents that I reviewed.

BY MR. SLATER:

Q. And I neglected to say something at the start that I had discussed with defense counsel prior, so this is a little bit of a tangent. We have an agreement and understanding that I will not be addressing any liability opinions or medical monitoring/medical surveillance opinions in this deposition. I just wanted to put that on the record so there wouldn't be a question later.

MR. INSOGNA: And as I said before we got started, we've traded some e-mails on that. We've not delineated what subjects in your understanding fall within the scope of that, but I understand that the medical monitoring claim is not at issue at this point, and I understand that you don't intend to ask questions about it.

MR. SLATER: Right. I don't intend to ask questions about opinions or discussion about the liability -- for example, how it occurred or whether it should have occurred -- meaning the contamination of

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the valsartan -- or the opinions provided as to whether or to what extent medical monitoring or medical surveillance would be appropriate in this case. Hopefully that little bit of clarity will answer any questions.

MR. INSOGNA: And as I said, yeah, we've traded e-mails on that subject. We've not delineated it, but I appreciate your -- what you said.

MR. SLATER: Okay. Thank you.

BY MR. SLATER:

Q. Okay, Doctor. Let's take down the deposition notice, and let's go to Exhibit 2, which is going to be the responses and objections we received to the deposition notice. Thanks.

[Exhibit 2 marked for identification.]

MR. INSOGNA: I'm going to provide to Dr. Catenacci.

MR. SLATER: Oh, perfect. If the doctor has it in front of him, we don't have to have it on the screen, then. Okay.

BY MR. SLATER:

Q. Doctor, looking now at Exhibit 2, which is titled Defendant's I-N-C.'s responses and objections to plaintiffs' notice of videotaped deposition of Daniel

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Catenacci, M.D.

Do you see that?

A. Yes.

BY MR. SLATER:

Q. Have you seen this document before?

A. Yes, it was provided to me.

Q. Did you read the document?

A. I looked through it, similar to the other ones.

Q. If you could turn to Page 2. There's a heading that says objections to document requests, and Number 1 was a request for various invoices.

Did you obtain and produce the invoices that were requested?

MR. INSOGNA: Object to form.

A. I provided my invoice to counsel.

BY MR. SLATER:

Q. We'll come back to the invoice in a few moments. Request Number 2, which is on Page 3, asked for notes for any work that was not documented in the invoices.

Is there any such documentation that you would have possessed?

A. Not that I'm aware of.

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Q. Number 3 asked for any notes or other documentation, including PowerPoints for any presentations, seminars, or classes given by Dr. Catenacci with regard to the risks and benefits of any angiotensin II receptor blockers or nitrosamines.

Do any such documents exist?

A. No.

Q. Is that because you have not given any presentations, seminars, or classes regarding the risks and benefits of angiotensin II receptor blockers or nitrosamines?

A. Yes.

Q. Number 4, which is on Page 4, asked for copies of any documents or articles relied upon for the opinions set forth in the report served, if not listed, in the report.

Are there any such documents or articles that you've relied on that you didn't list somewhere in the report?

A. No.

Q. And we're going to obviously -- rephrase. We're going to come back to this, but there's been a few different versions of the report, so when I'm talking about the report, I'm talking about the most

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up-to-date version, so -- you understood that?

A. Yes.

Q. Looking at Request Number 5 on Page 4. Copies of any documents or articles reviewed in connection with the report served, whether or not listed in the report or attachments thereto.

Does any such document exist?

A. I think there would be many documents that would fall into that category that I looked at that I didn't include or reference.

Q. But they haven't been produced to us, to your knowledge; correct?

MR. INSOGNA: Object to form.

BY MR. SLATER:

Q. Well, let me ask the question more directly. To your knowledge, have any documents or articles that you reviewed in connection with the report that are not actually listed in the report or the attachments to the report have been produced to us?

A. I'm not aware of that.

Q. Number 6 on Page 5 -- any illustrations, PowerPoints, images, charts, tables, or demonstrative exhibits that may be used by or with Dr. Catenacci in connection with the Daubert hearing or trial testimony

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in this litigation.
Do you have any such -- rephrase. Do you have any such documentation that you've produced?
A. No.
Q. Number 7 -- well, let me ask you this, going back to 6. Is there any such documentation that you have not produced, meaning that you have it but you haven't produced it?
A. No.
Q. Number 7. Documentation of any research grant the witness has been provided to study any angiotensin II receptor blockers or nitrosamines or health effects potentially related thereto.
Does any such documentation exist?
A. No.
Q. Is that because you've done no such research or study?
A. That's correct.
Q. Number 8 on Page 6. Documentation of any research the witness has performed with regard to any angiotensin II receptor blockers or nitrosamines or health effects potentially related thereto.
I don't believe any such documentation has been produced. Is that because you have not performed

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any such research?
MR. INSOGNA: Object to form.
A. Yes.
BY MR. SLATER:
Q. Number 9 requested copies of any documents including protocols or information about the medication side effects available to the witness from any hospital or academic institution where he has worked, had an appointment or had privileges, which set forth information related to the risks and benefits of any angiotensin II receptor blocker or nitrosamine.
First of all, did you attempt to identify any such documents to produce to us?
A. No.
Q. Do you know if such documents exist, for example, at the institutions you work at currently?
A. I do not.
Q. For example, there might -- rephrase. I would think the hospital that you work at there's a formulary and that there would be lists of the different medications, including their risks and benefits.
Did you consult that at all regarding any of the drugs that are at issue here -- the valsartan

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drugs?
MR. INSOGNA: Object to form.
A. I did not.
BY MR. SLATER:
Q. Were you asked to obtain such documents?
A. I was not.
Q. Number 10 requested any documents or other communications the witness has received from any person or entity with regard to nitrosamine impurities in any angiotensin II receptor blocker or other drug outside of information provided by counsel who retained the witness.
So do any such documents or communications exist, to your knowledge?
A. Everything that has been disclosed was provided.
Q. By counsel?
A. Yes.
Q. And Number 11 requested any communications from the witness to any person or entity with regard to nitrosamine impurities in any angiotensin II receptor blocker or other drug outside of communications to counsel who retained the witness.
Do any such communications exist?

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A. Anything that's been disclosed has been provided.
Q. Outside of documented communications, for example, in an e-mail or a letter, have you had any such oral communications with anybody other than counsel about the nitrosamine impurities in the angiotensin II receptor blockers?
A. No.
Q. Have you discussed the subject matter of this litigation or the report you wrote in this litigation with anybody other than counsel?
THE REPORTER: I'm sorry. Was there an answer?
A. No.
BY MR. SLATER:
Q. Finally, Number 12 requested any textbook referenced by the witness in forming his opinions.
Are there any such textbooks?
A. No. Other -- sorry.
MR. INSOGNA: Are you asking other than what's listed on the reliance list?
BY MR. SLATER:
Q. Well, no, my question is, first of all -- well, yeah. Let me phrase it. To the extent that a

textbook was referenced in the report as having been relied on, were those produced?

MR. INSOGNA: And counsel, I would just note our objection to things that the witness had only in hard copy form.

MR. SLATER: Well, I just want to -- we can talk through what the logistics would have been. I just want to find out what was or wasn't done, and then we can talk through. I don't think there's anything to object to yet.

BY MR. SLATER:

Q. My just question, Doctor, is this. Did you -- well, first of all, let's ask this. I've read your report, but let's state for the record.

Did you actually rely on any textbook to form your opinions that are set forth in your report?

A. No. Most of the -- all the references that I use are journal articles. They're not textbooks per se.

Q. Okay, we can put the -- you can put aside that response to deposition notice. I'm hopeful -- well, actually, we'll get to that. We'll find out what I'm hopeful about later, and we'll talk about it during lunch or something.

When were you first contacted by anybody with regard to this litigation?

A. I think it was back in March of this year.

Q. March of 2021?

A. Yes.

Q. Who contacted you?

A. Alex Lagos.

Q. Who is Alex Lagos?

A. He's a counsel for Greenberg Traurig.

Q. An attorney at Greenberg Traurig?

A. Yes.

Q. Do you know how -- rephrase. Do you know why Alex Lagos contacted you, as opposed to somebody else? Do you know how he got to you?

A. I looked back at that e-mail, and she indicated that another doctor who I know in Miami had referred her to me.

Q. Who was that doctor in Miami?

A. Greg Lockhart (ph).

Q. Greg Lockhart? What type of physician is Greg Lockhart?

A. Same as me. He's a GI medical oncologist.

Q. And I think when I said Alex Lagos, I think I said he but you said she. So did I misstate?

A. Yes. I think it's Alexandra, maybe.

Q. I want to get that accurate, so I apologize if I misstated. When you were contacted in March of 2021, what was your understanding as to what you were being asked if you were willing to do? Let me ask it differently.

When you were first contacted in March 2021, what was your understanding as to what you were being asked to do?

A. I was being asked to familiarize myself with the issue at hand and ultimately be able to provide a number of different things in a report ultimately, which was first starting with a general background of what is cancer, carcinogenesis, and with a focus on risk factors and focusing on some specific cancers that were listed in the litigation, to provide statistics in terms of incidences of these cancers and cancers overall, and then to evaluate whether or not ultimately the question at hand -- which was the impurities of NDMA and NDEA -- whether or not they would lead to an increased risk over standard rates of cancer.

Another thing they asked was whether or not putative exposures to these agents would lead to

the need to monitor patient -- people or patients that had these exposures and do anything different than what would be routine surveillance over time.

Q. Did you have an understanding as to who was retaining you when you actually agreed to go forward as an expert in this case?

A. Yes, I think I was made clear that they were counsel for the defense of this -- of one of the pharmaceutical companies that was involved, which I believe was Teva.

Q. So you understood -- I'm sorry. I didn't mean to interrupt.

A. And so the answer to your question is, yes, I knew that that was where they were coming from.

Q. So you understood that you were being retained by attorneys from Greenberg Traurig to be an expert on behalf of Teva in this litigation?

MR. INSOGNA: Object to form.

A. Yes, that's what my understanding was.

BY MR. SLATER:

Q. Other than Alex Lagos, have you spoken to any other attorneys in connection with this litigation?

A. Yes.

Q. Who else have you spoken with?

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A. Nick Insogna. Katie -- forgive me -- last name. I don't have all the names.
Q. Well, what I want to know is the names that you can recall.
You told me Katie, who's present at the deposition; right?
A. Yes.
Q. Had you ever spoken to her before today?
A. Yes.
Q. When did you first speak to Katie?
A. I don't know exactly, but it was often in calls along with Nick.
Q. Do you know what law firm Katie works with?
A. I believe the same law firm.
Q. What other attorneys, if any, have you spoken with about this case or your report?
A. There was a couple of other attorneys, I believe, from other defendants, the names of which I didn't memorize and I don't know. But that was during a call that we had on Saturday, and also a meeting on Wednesday.
Q. When you refer to a call on Saturday, you're talking about two days ago?

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A. Yes.
Q. And when you refer to a meeting on Wednesday, are you talking about last Wednesday, about five days ago? Other than the two calls that -- well, rephrase.
The meeting last Wednesday -- was that also a call, or was that in person?
A. That was on site here in person, but the attorneys that I mentioned from other defendants were on Zoom.
Q. Do you know who from other defendants attended -- what lawyers attended on Wednesday of last week?
A. I don't have the names.
Q. Do you know who in terms of lawyers for other defendants attended the call on Saturday, two days ago?
A. Same -- the same attorneys.
Q. I think Clem Trischler -- Clem is in the room -- rephrase.
I believe Clem Trischler is present. Had you ever spoken with him before today?
A. No, not that I'm aware of.
Q. Are there any other attorneys whose names

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you do recall who you've spoken to about this case or your report?
A. Outside of what I just mentioned, no.
MR. SLATER: Chris, if we have Dr. Catenacci's invoice, I'd like to put that up on the screen, please -- or invoices.
BY MR. SLATER:
Q. Great. Doctor, on the screen we have what we're marking as Exhibit 3 to your deposition, which is --
[Exhibit 3 marked for identification.]
MR. INSOGNA: Adam, we don't have that up on the screen.
MR. SLATER: You don't have it on the screen?
MR. INSOGNA: I'm not showing it, no.
MR. SLATER: I'm looking at it on the screen.
MR. INSOGNA: I see it. I see it. Yes.
MR. SLATER: Okay. I'll start over.
BY MR. SLATER:
Q. In front of you is what we've marked as Exhibit 3, which is our under -- rephrase. On the screen we have Exhibit 3, a June 15, 2021, letter, that

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you wrote to Alex Lagos.
What is that document?
A. That looks like it's the first invoice that I submitted for this work.
MR. SLATER: Chris, can you blow up that front page a little bit, please, so I can read it? Perfect. That's good.
BY MR. SLATER:
Q. This states that as of June 15, 2021, you had spent 19 hours at $700 an hour and the total was $13,300; correct?
A. Yes.
MR. SLATER: And Chris, can you scroll down to the next page? I want to see what other information's attached, please.
MR. GEDDIS: What page? Adam, can you hear me?
MR. SLATER: I would like to get the actual invoices, too, or did we only get the cover letter?
MR. GEDDIS: I think that's --
MR. SLATER: I can't hear you, Chris.
MR. GEDDIS: Adam, it's only one page. I don't think there's -- I don't know if there's an

additional --
MR. SLATER: Okay, let me go back into it then. All right. You can scroll down a little more so we can see the body of the document again. Can you blow it up to where it was? Okay.
BY MR. SLATER:
Q. Doctor, was there any enclosure to this letter, or was this simply your -- this -- rephrase.
Was there any enclosure, or was this letter your entire invoice?
A. That is my entire invoice.
Q. Do you keep records of the time that you have spent working on this case and what you were doing when you were spending time on this case so that if someone asked you for an itemized list of how you got to the 19 hours, that you would be able to provide that?
A. I don't keep it written, no.
Q. How did you know you spent 19 hours as of June 15? Was that an estimate?
A. I looked back at the dates that I knew I was reviewing and reading and added time that I spent up writing, because this was also the draft report.
Q. Between June 15, 2021, and today, which is

September 13, 2021, how much additional time have you spent on this matter?
MR. INSOGNA: Object to form.
A. Depends which dates. Since this invoice?
BY MR. SLATER:
Q. Since the invoice and up to before we started this deposition today, how much additional time have you spent on this matter?
A. There is a second invoice that has some of that time already documented, and that was up unto this submission of my report, and then since then I'd have to go back and calculate it.
Q. Let's go now to the second invoice letter, which we'll mark as Exhibit 4.
[Exhibit 4 marked for identification.]
BY MR. SLATER:
Q. On the screen we have Exhibit 4, which is in August.
MR. SLATER: Can you scroll up to the date, please, Chris? Okay.
BY MR. SLATER:
Q. On the screen we have Exhibit 4, which is an August 2, 2021, letter that you sent to Nicholas Insogna at Greenberg Traurig.

Is that your second invoice in this case?
MR. INSOGNA: Speak up a little bit. My voice cracked.
A. Yes.
MR. SLATER: Chris, can you blow it up a little more, please? Okay.
BY MR. SLATER:
Q. According to this invoice, after your June 15, 2021, invoice and up till August 2, 2021, you spent an additional 94.5 hours.
Is that correct?
A. Yes.
Q. Did you keep any itemized notes or lists of what time you spent and what you did during those time blocks, or did you do what you told me earlier, which was you just went back to see when you worked on it and estimated?
MR. INSOGNA: Object to form.
A. The latter.
BY MR. SLATER:
Q. Is there any other invoice after August 2nd?
A. No, not yet.
Q. How much time have you spent after the

August 2nd invoice was sent up until before we started the deposition on this case?
A. Like I said, I'd have to go back and look at and calculate it.
Q. Can you give me your best estimate of how much time you've spent between August 2, 2021, and today?
A. Many hours.
Q. Can you give me some sense of what you mean by that?
A. I have to go back and look at the actual times that I spent on it.
Q. So you have no -- you're not able to estimate in any way?
MR. INSOGNA: Object to form.
A. I'd have to go back and look at the actual times that I blocked off that I know, for example, and add them up, and I haven't done that yet. I was going to do it after this deposition.
BY MR. SLATER:
Q. In terms of actual preparation for the deposition, do you know how much time you've spent actually preparing for the deposition?
I'm not talking about the general work

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you've done on your report, but focused work to try to prepare yourself for this proceeding.

MR. INSOGNA: Object to form.

A. Like I said earlier, it depends on the definition of that, because I've been essentially preparing for this since the get-go, but certainly after the submission of the report when I knew that a deposition was the next step, that was initially when I started to really prepare, and then really focused preparation in the last few weeks with more dedicated time to it.

BY MR. SLATER:

Q. Working backwards, in the last few weeks, can you estimate how much time you've spent preparing for the deposition?

A. At least three to four hours a day, and in some days more than that. Like, for example, the last few weekends were basically doing it all day.

Q. And that's focused preparation for the deposition?

MR. INSOGNA: Object to form.

A. Could you explain -- define what that means?

BY MR. SLATER:

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Q. What I mean is this. That's -- the time you just described is time you've spent with the focus on preparing for this deposition?

MR. INSOGNA: Same objection.

A. Meeting, having -- reviewing -- re-reviewing things that I had read before, re-reviewing my report, reviewing new information that came along like the depositions of the expert witnesses, et cetera, the -- all of the reports of the defense that came out after I submitted my report. All of that, I mean, I think, would qualify as preparing for this December, and so yes, all of those hours.

BY MR. SLATER:

Q. You said reviewing the reports of all of the defense experts.

Have you, to your knowledge, reviewed the reports of all the defense experts?

A. I believe so, yes.

Q. Did you rely on those reports in any way in forming the opinions that you're providing here, or did you see them all after the fact?

A. I saw them all after the fact.

Q. So if I understand, you're not relying on the other defense expert reports for your opinions

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here; correct?

A. Not relying on them, no.

Q. Bear with me. I got to write something down.

Have you seen the deposition of Dr. Pennegrafe (ph)?

A. I have not. That was on Friday, I think.

Q. Okay, let's take down this invoice, please.

Do you know how much time or can you estimate how much time you've spent in actual discussions or meetings with counsel as part of your preparation for the deposition?

A. There was the three hours I mentioned on a Zoom call on Saturday, the meeting in person here, hybrid with Zoom on Wednesday, which I believe was five or six hours. And then there were various calls. This is just for the deposition preparation?

Q. Correct.

A. Yeah, then there were various short calls on the phone that probably amounted to less than an hour, an hour, approximately.

Q. In terms -- so rephrase. In terms of actual meetings, whether in person or virtual or by

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telephone, you're estimating about 10 hours for those meetings?

A. Right.

Q. Do I understand that correctly?

A. And that's not e-mail communication.

Q. And I'm certainly not going to ask you for the contents of any e-mails, but is it fair to say that you've had many e-mail communications about and in preparation for this deposition?

MR. INSOGNA: Object to form.

A. In various aspects of communication, yes.

BY MR. SLATER:

Q. What do you mean by "in various aspects of communication"?

A. About the report, where to be for the deposition, like logistics. All kinds of different aspects regarding the deposition.

Q. And those aspects would include substantive communications; correct?

MR. INSOGNA: Object to form.

A. Not usually. Most of those would be by communication, in person or on the phone, or by Zoom.

MR. SLATER: All right, Chris.

BY MR. SLATER:

Q. If we could -- and I think you have the reports there, Doctor. If you have your initial report of August 2nd, 2021, that's the next exhibit I'd like to go to. We'll mark that as Exhibit 5.

[Exhibit 5 marked for identification.]

MR. SLATER: And just logistically for our end, I assume for Chris and the court reporter, we still can mark that document as Exhibit 5 even if we don't put it up on the screen; right?

MR. GEDDIS: That's producing (ph) it all on mine.

MR. SLATER: I just want to make sure it's being handled. That's all. I'm not going to get into the details. I just want to make sure it didn't get lost. Okay.

THE REPORTER: From my end, as long as he puts it in the Dropbox, I'll mark it as an exhibit.

MR. SLATER: Terrific.

BY MR. SLATER:

Q. Okay, Doctor, do you have in front of you x5, your August 2, 2021, report in this case?

A. I do.

Q. When you wrote this report, did you attempt to set forth each of the opinions you had

reached in this case?

A. Yes.

Q. And did you in fact set forth the opinions you had reached in this case when you signed your August 2, 2021, report?

THE REPORTER: I'm sorry. Did you answer?

A. Yes.

BY MR. SLATER:

Q. In the course of the report itself, you talk about or speak to various facts that you obtained either from studies or from documents that were provided, et cetera.

Did you reference and discuss those facts that were most important to you in forming your opinions in the report?

MR. INSOGNA: Object to the form.

A. Yes.

BY MR. SLATER:

Q. When you wrote this report, did you write it with care and precision?

A. To the best of my ability, yes.

Q. Did you choose the words that you used in the report with care and precision?

A. Yes.

Q. And before you signed the report, did you carefully read it to make sure it said what you wanted it to say?

A. Several times for substance and -- for the substance particularly. The details and spelling and things like this, to the best of my ability, although even now when I read it every now and then I find a typo.

Q. Before you signed the report, did you ensure that the references that are found within the report were accurate in the sense that if you put a reference number, that it actually correlated to the actual document that you meant to reference?

A. I tried to, yes.

Q. When you say you tried to, what does that mean?

A. As you know, after I submitted the report, it was noticed that some of the references got mixed and that needed to be corrected, and hence the amended report that corrected that.

Q. When you say the references got mixed, what does that mean?

A. It means that they got referenced at the wrong location within the text.

Q. Did you find any examples where you had referenced an article for a proposition or something you stated in the report and in fact you didn't intend to reference any source?

A. Not that I'm aware of, no.

Q. In addition to the list of references that are numbered, there's another list that we were provided as an exhibit of materials considered.

Did you read all of the -- and we're going to get to the specific document, but did you read all of the articles or other documents that are listed on your list of materials considered? Did you read every single one of those documents that are listed?

A. Yes, to different amounts of detail and different numbers of times. Some were more important than others.

Q. Let's go now to the next exhibit, which is going to be the August 25, 2021, report.

[Exhibit 6 marked for identification.]

MR. INSOGNA: Set that one aside so you don't confuse them. Adam, when you say August 25, I believe that's the one we told you to disregard and we sent the August 27th report that Dr. Catenacci provided.

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MR. SLATER: Yeah, I just wanted to make sure that I marked each of the documents that were produced to us so I can ask him about them. I just feel like I want to be -- I just need to be thorough to make sure everything's identified and I get everything in context. We're going to get to the August 27, but I'm just going in order of what was served to us.
BY MR. SLATER:
Q. Doctor, do you have the -- oh, you're getting it. Okay.
A. That's --
MR. INSOGNA: Yeah.
BY MR. SLATER:
Q. Doctor, looking now at Exhibit 6, which is the August 25, 2021, report we were provided.
Have you seen that report before?
A. Yes.
Q. And I see that your signature is at the end of the report after Page 60.
Did you sign this document?
MR. INSOGNA: Object to form. (Inaudible) document.
A. Looks like my signature's there, but it's not actually -- my name is in there with my

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credentials, but there's not an actual signature.
BY MR. SLATER:
Q. The version that you're looking at doesn't have a signature on it?
A. August 25th on Page 47?
Q. Go further. If you go past Page 60, there is a signature after Page 60.
A. I only have Page 60. That's where my version ends that I have here in front of me.
Q. In looking at the signature on this report, it seemed to look the same as the signature on the prior version. It looks like an electronic signature.
Is that accurate?
A. Yes.
Q. If you look at the very first page of the August 25, 2021, report, the bottom left-hand column, or bottom left of the page.
You see where it says active and then there's a number after that?
A. Yes.
Q. Do you know what that refers to?
A. I do not.
Q. That's not something you placed on the

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report; correct?
A. No.
Q. And just to be clear, why was the August 25, 2021, report sent to us after we had been served the August 2, 2021, report?
A. I believe it was to correct some of those noted mistakes with the referencing.
Q. Was any change made to the substantive content of the report?
A. No.
Q. Now let's go to the August 27, 2021, report, which we'll mark as Exhibit 7.
[Exhibit 7 marked for identification.]
BY MR. SLATER:
Q. Do you have that in front of you?
A. Yes.
Q. Oh, I'm sorry. I'm sitting here waiting for you to get it and you're waiting for me to realize you had it.
A. This is the one we started with that I had from the get-go.
Q. Looking now at Exhibit 6, the August 27, 2021, report.
To your knowledge, is that the most

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up-to-date version of the report and exhibits?
A. Yes.
Q. Was this version of the report provided to, as you stated earlier, correct the mistakes with the references?
A. Yes, I believe so.
Q. Now, it's my understanding that with the exception of Exhibit B, which we'll get to -- well, let me ask the question differently. Exhibit A to this report, the August 27, 2021, report, is a CV.
Is that your current and up-to-date CV?
A. No, I have -- I usually update it monthly pretty much, so I have Number 1 (ph).
Q. Is there anything that's been added to this CV that relates in any way to the subject matter of this litigation?
A. No.
Q. If you could, I'd like -- rephrase. I'd like to walk through a little bit of your CV and ask you a couple questions if we could, please.
A. Okay.
Q. Let's go, if we could, to Page 3. There's a heading original articles.
A. Yes.

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Q. Are those articles that you have authored or coauthored?
A. Yes.
Q. And those are found in the peer-reviewed literature, is my understanding?
A. Yes.
Q. Do any of your published articles that are listed here address specifically any of the issues at issue in this litigation?
MR. INSOGNA: Object to form.
A. No, not specifically.
BY MR. SLATER:
Q. I'm going to go through a few more specific questions just to make sure we're all on the same page.
Do any of these articles relate to or discuss NDMA, NDEA, or nitrosamines in any way?
A. None of the original articles, no.
Q. Have you ever conducted or participated in any way in a study regarding the health effects of NDMA or NDEA or other nitrosamines?
A. No.
Q. Do you have any plans to conduct such a study?

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A. No.
Q. Have you ever made a submission to an IRB, an institutional review board, regarding such a study?
A. No.
Q. Have you -- rephrase. Do any of these publications address in any way the risks and benefits of valsartan or other drugs in that medication class?
A. No.
Q. Do any of your articles address causation of cancer due to exposure to chemicals?
A. No original articles, no.
Q. When you say no original articles, I just want to make sure you're not making a distinction to something else. What do you -- so what do you mean by that?
A. You had asked me at the beginning of this line of questioning about where -- on Page 3 when it was talking about original articles. But if you look at further pages, there are other types of articles that I would publish, and those include editorials, commentaries, reviews of given topics, and consensus statement and guidelines, book chapters, et cetera, so none of the work that would be considered original work where I'm doing actual new research has to do with any

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of those questions you asked.
Q. Go if you could to Page 9, please.
A. Okay.
Q. There's a heading consensus statements and guidelines.
A. Yes.
Q. Do any of the materials listed under that heading address any of the issues specific to this litigation?
MR. INSOGNA: Object to form.
A. No.
BY MR. SLATER:
Q. For example, do any address nitrosamines in any way?
A. No.
Q. Do any of them address the risks or benefits of valsartan or similar drugs?
A. No.
Q. Looking now on Page 9 of the heading book chapters. The same question. Do any of those address the specific issues in this litigation?
MR. INSOGNA: Same objection.
A. No.
BY MR. SLATER:

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Q. Do any of them address nitrosamines in any way?
A. No.
Q. Do any of them address the risks and benefits of medications like valsartan to treat hypertension?
A. No. One thing I noticed on the book chapters -- because I didn't realize that that's where it was -- is Number 95.
Q. Okay.
A. Which is our society, the American Society of Clinical Oncology, or ASCO -- A-S-C-O -- where I co-wrote with my colleague this self-evaluation program, which is how medical oncologists get certified and get recertified, so this is the study manual. And so in that encompasses all GI cancers, and so there are background sections that may allude to risk factors and other things that would come up with various cancers.
And so I think there would be probably references that nitrosamines have been reported to be associated with gastric cancer and that other reports have shown the opposite and that there's no clear consensus on those dietary studies.
Q. This was authored, it looks like, 2021; is

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that correct?
A. Yes. Yes.
Q. Do you know when in 2021 you authored it?
A. Well, this was a process over a year, and that they continually elicit us with updates for new trial outcomes and to add to the guidelines for treatment, so it's an ongoing process. I think it came online in the late spring, early summer, for people using it to study for their board exams.
Q. As you did different iterations of that document, would you have been red-lining so that you could see each of the changes and be able to know when you were modifying the language as you went forward?
A. I would be going back to the most recent version and adding to it and then resubmitting the change -- the new version of the document.
Q. There's a second doctor listed there, B.N. Polite, or "polite"?
A. "Polite," yeah.
Q. Polite? Who is that?
A. He's a colleague of mine at the university. He's also a GI medical oncologist.
Q. Did Dr. Polite also contribute to the writing of this document?

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A. Yes. We divided up different cancer types, basically, and assigned them to each other.
Q. And what exactly is, again -- I just want to make sure I understand -- the ASCO -- A-S-C-O -- self-evaluation program that this was published in? What is this?
A. It's a material source that oncologists would use to prepare for their board exams. So it has background sections on the cancer, but most of it's focused on the treatment guidelines, treatment standards, clinical care of patients in various settings of the disease. And then there are usually question books that come along with it so people can prepare for their board exam.
Q. Did you provide that document or at least the chapter that you authored to counsel to produce to us?
A. No, but I'm happy to do so if that's required.
Q. Did you disclose anywhere in that chapter that you had been retained by a defendant in this litigation where one of the questions was the association of certain nitrosamines with certain cancers? Was that disclosed in any way there?

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MR. INSOGNA: Object to form.
A. This particular self-evaluation program, no, actually wasn't published when I was talking to them mostly; right? But in my actual report and on my reliance list is a reference similar to that flavor, which is under the review section of my publication, which is Reference 80, which is -- was written by my fellow and -- which is a trainee -- and review articles are common to do like that, and that's the background on gastroesophageal cancer.
And a similar reference is in there in terms of noting a number of potential associations with various cancers, with various gastroesophageal cancers, and pointing out that there are some that do and some that don't suggest an association of nitrosamines with stomach cancer.
And that's in my report when I'm talking about risk factors for gastric cancer, and the dietary studies that are lower down in my report. I'm -- that.
BY MR. SLATER:
Q. So if I understand correctly in publications that you just identified, Number 80 and Number 95, you state that there is literature that would support an association with certain gastric

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cancers and there's other literature that is less definitive.
Is that a fair understanding?
MR. INSOGNA: Object to form.
A. We were just noting data that's out there that's not definitive in a section that's talking about risk factors for stomach cancer, to point out that studies have been done. And it's not an exhaustive reference list either in those reports. There are token references that the fellow decided to put in, but there are clearly more references that one could include on that specific topic.
BY MR. SLATER:
Q. From a macro perspective, you would agree that there's a potential association between NDMA and NDEA and certain cancers? As a general statement, you would agree with that; correct?
MR. INSOGNA: Object to form.
A. No.
BY MR. SLATER:
Q. So you think that anybody who would say that there's a potential association between NDMA or NDEA and any human cancer would be incorrect?
MR. INSOGNA: Same objection.

A. I think that based on my review, as you can see in my report, I would disagree and I would say that that's an incorrect statement.
BY MR. SLATER:
Q. So your position is anybody who has any interest in whether or not nitrosamines, including NDMA and NDEA, cause cancer in humans, you would say to them you can stop researching it, you can stop looking at it, there's no potential for these substances to cause cancer in humans? It's a closed book, there's no reason to look at the subject further?
MR. INSOGNA: Object to form. Misstates testimony.
A. I didn't say that, no. I said that right now if somebody concluded that there is an association, that would be incorrect. I didn't say that further studies should or shouldn't be done.
BY MR. SLATER:
Q. What if -- well, rephrase. Do you agree that there is a potential association between NDMA and NDEA and certain cancers in humans?
MR. INSOGNA: Object to form.
A. It is -- they are listed as probable carcinogens in humans by the IARC.

BY MR. SLATER:
Q. And you don't disagree with that; right?
A. I don't agree with that statement, no. I don't disagree --
Q. You disagree -- go ahead. I'm sorry.
A. No, I wanted to clear up. I don't agree with the IARC statement.
Q. I think I skipped over your editorials commentaries heading on Page 8. I think when you told me about your Reference 80, it reminded me that I had skipped a page, so --
Looking at Page 8 of your CV, there's a heading editorials/commentaries?
A. Yes.
Q. And those are References 65 to 74; correct?
A. Yes.
Q. Do any of those publications address the issues in this litigation?
A. No.
Q. Do any of those publications discuss in any way nitrosamines or NDMA or NDEA?
A. No.
Q. Do any of those publications discuss the risks or benefits of valsartan or similar medications?

A. No.
Q. Looking now on Page 8 at the heading reviews, which encompasses References 75 to 83. We've talked about Reference 80 just a moment ago.
With the exception of Reference 80, do any of these publications address nitrosamines or NDMA or NDEA in any way?
A. No.
Q. Do any of them address the risks or benefits of valsartan or similar medications?
A. No.
Q. And just to close the loop on Reference 80, other than the specific part that you've told us about, is there any other discussion of nitrosamines?
A. No. It's one or two sentences in that section.
Q. I think we got through consensus statements and guidelines and book chapters. Looking now at the bottom of Page 9, there's a heading original articles under revision, submitted or in preparation. Do any of those references, which are listed as 1 through 5, address nitrosamines in any way?
A. No.

Q. Do any of them address the risks or benefits of valsartan or similar medications?
A. No.
Q. On Page 10, there's a heading that says research support, current grant support.
Do any of those listed address the issues in this case?
A. No.
Q. Specifically, the potential risks of nitrosamines such as NDMA or NDEA?
A. No.
Q. In the middle of Page 10 there's a heading submitted/planned submission pending grant support.
Do any of those items address nitrosamines or the potential risks of nitrosamines?
A. No.
Q. Do any of them address the risks or benefits of valsartan or similar medications?
A. No.
Q. And I think I forgot to ask that last question regarding the current grant support. Do any of those items address the risks and benefits of valsartan or similar medications?
A. No.

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Q. Going to the heading on Page 10 that says past grant support, do any of those items address nitrosamines or the potential risks of nitrosamines in any way?
A. No.
Q. Do any of those address the risks and benefits of valsartan or similar medications?
A. No.
Q. On Page 11, there's a heading that says oral presentations, invited speaking, international meetings/conferences. Do any of those international meetings or conferences reflect speaking that you've done regarding nitrosamines?
A. No.
Q. Have you ever spoken, other than in the context of this case, regarding the potential risks of nitrosamines?
A. No.
Q. Other than in this case, have you ever spoken regarding the question of whether NDMA or NDEA can cause cancer in humans?
A. No.
Q. Do any of these speaking engagements address the risks and benefits of valsartan or similar

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medications?
A. No.
Q. You said no; correct?
A. I said no. Correct.
Q. Thank you. Then there's a -- rephrase. Looking at the bottom of Page 12 there's a heading that says national, and I suppose these would be speaking engagements that you've had in the United States?
A. Yes.
Q. Do any of those speaking engagements address in any way nitrosamines or the risks of nitrosamines?
A. No, they do not.
Q. Do any of them address the risks and benefits of valsartan or similar medications?
A. No, they do not.
Q. On Page 15 there's a heading that says regional. Do any of those speaking engagements address nitrosamines in any way?
A. No, they do not.
Q. Do any of them address the risks and benefits of valsartan or similar medications?
A. No, they do not.
Q. On Page 16 there's a heading intramural.

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Do any of those intramural speaking engagements address nitrosamines or the risks of any nitrosamines?
A. No, they do not.
Q. Do any of them address the risks and benefits of valsartan or similar medications?
A. No, they do not.
Q. On the bottom of Page 17, there's a heading that says invited elected service.
Do you see that?
A. Yes.
Q. Do any of those -- I'm going to refer to them as appointments. Do any of them bring with them -- well, rephrase.
Looking at the bottom of Page 17 where it says invited elected service, what is that encompassing?
A. This is a mix of different things, including intramural positions. Like the first one listed there to be on the clinical trial research committee, which reviews new trials and provides scientific input on how they can be improved before they actually get passed through the IRB, for example.
Some of these are -- like the Alliance (ph) one listed there, the third one -- is what's

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called a cooperative group of multiple different institutions that are cancer centers that come together to do studies together, and so there are committees in order to get trials through and passed, et cetera, and so I served on that, for example.
Some of these are philanthropic groups that I've been asked to serve on the medical advisory committees, you can see there. So it's a mix of -- the ASCO, American Society of Clinical Oncology, set the self-evaluation program that I just -- we were talking about for medical oncologists to get board-recertified. That was an invitation to write that chapter by the society, for example.
So that's the flavor of what those types of positions -- and some of them are volunteer work, et cetera -- are.
Q. Do any of those positions or the work you've done in connection with those positions address in any way nitrosamines or the risks of nitrosamines?
A. No.
Q. Do any of them address the risks and benefits of valsartan or similar medications?
A. No, they do not.
Q. Looking at Page 18, there's a heading

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editorial activities, and it indicates that you're an ad hoc reviewer for various medical journals; correct?
A. Yes.
Q. That means a peer reviewer; correct?
A. Yes.
Q. Have you ever peer-reviewed any article or publication addressing the potential risks of nitrosamines, including NDMA or NDEA, to humans?
A. No.
Q. Same question regarding potential risks to animals.
A. No.
Q. On Page 18, there's the heading associate editor, and then another one that says editorial board membership.
With regard to those editorial positions, have you ever had occasion to look at or be involved with an article addressing nitrosamines or the potential risks of nitrosamines to humans?
A. No.
Q. And in those positions have you ever addressed a publication regarding the risks and benefits of valsartan or a similar medication?
A. No.

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Q. And with regard to your peer review work and your editorial work, one of the important things is the precision and clarity and accura -- rephrase. Let me ask this.
With regard to the peer review and editorial work, is it fair to say that the accuracy of what is written in an article that's published in the literature is important?
A. Absolutely.
Q. In those positions I assume you endeavor to make sure that the references to the statements made within the articles are accurate; correct?
A. We do that -- for example, as an associate editor I would be looking at that, but also there are staff that review those types of spelling language because we get a lot of submissions, for example, where English is not the first language, and so there's a lot of editing that's done.
The first pass of deciding whether an article has merit is looking at the science and looking at the substance. The other stuff, like spelling, wording, and language, the references, things that are technical like that, are done after the decision is made whether or not this is worth publishing in our

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journal. And that's after several reviews back and forth with the authors.
Q. When a document is finalized through the editorial process that we're discussing, are the references all supposed to be accurate at that point?
A. At the end when it goes online or when it gets published, yes. That's what we strive towards. Of course, there are always mistakes to that extent, unfortunately.
Q. Even in the peer review process, there can be some mistakes regarding a reference? That can happen; right?
A. Absolutely. All --
Q. The fact that someone -- I'm sorry. I didn't mean to interrupt.
A. I was going to say, even when I'm publishing myself, I review my manuscript literally hundreds to thousands of times over the course of when it's being written. Inevitably there will be certain spelling errors or things that you only see after the fact after you see it online.
The same thing when doing presentations. You present -- you're preparing for a presentation multiple times, and then as you're doing the

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presentation sometimes you see, "How did I miss that?"
All of those -- I mean, those types of things happen to everybody. We're human. But it doesn't effect the essence of the message that's being -- attempted to be brought forth.
Q. So the fact that there may be some errors with some references or spelling or something like that from your perspective doesn't undercut the discussion of the science and the substance, as you phrased it earlier? Do I understand that correctly?
MR. INSOGNA: Object to form.
A. That's right.
THE REPORTER: Sorry. Did you say "right"?
A. I said "that's right."
THE REPORTER: Thank you.
BY MR. SLATER:
Q. There's a heading on Page 18 that says clinical protocols.
A. Yes.
Q. And for the purpose of this question, I'm going to include all the clinical protocols that you've listed in your CV, because there's a whole series of them that follow that heading in different categories;

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right?
A. Yes.
Q. With regard to all of those, do any of those clinical protocols address nitrosamines or the potential risks of nitrosamines to humans or animals?
A. No.
Q. Do any address valsartan, the risks and benefits of valsartan or similar medications?
A. No.
Q. Going now to Page 23, the next heading is teaching activities?
A. Yes.
Q. In your teaching, have you ever taught -- well, rephrase.
In your teaching, have you ever taught specifically with regard to nitrosamines or the risks of nitrosamines to humans or animals?
A. No.
Q. Have you ever taught regarding valsartan or similar medications and their risks and benefits?
A. Probably did when I was a resident and fellow when we're teaching other students. Maybe even now when I'm rounding as an inpatient attending with medical students, because we take care of patients who

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are sick who are on these medications, so these types of conversations come up in terms of treating patients with blood pressure medication, which is very common.
Q. So an issue could come up -- just because a patient might be utilizing that type of medication -- it could be part of the discussion?
A. Right, because some of these are -- I mean, what I'm listing here are different ways of teaching, and one of the predominant ways that I teach is through routine patient care with medical students, residents, and fellows.
And so when we're talking about patients who are sick, inevitably they're -- many of them are taking blood pressure medicine. So I'm sure that these types of topics would have come up.
Q. I'll try to be more precise, then. And I understand what you said. With regard to your teaching activities, have you ever taught specifically with regard to the risks and benefits of valsartan or similar medications, other than in the context of maybe discussing a particular patient's list of medications or what's going on in that patient's background?
A. Just that. Nothing outside of that.
Q. And under teaching on Page 24, you then

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have a heading about those research trainees and mentees that you've mentored. Has any of that work addressed nitrosamines or the risks to humans or animals of nitrosamines?
A. No, it has not.
Q. Has any of that work addressed the risks and benefits of valsartan or similar medications to valsartan?
A. No, it has not.
Q. And that would be true all the way through to the end of your CV on Page 27? That covers that whole category; correct?
A. Yes.
Q. We can put aside your CV. I think we got through it.
MR. INSOGNA: Adam, are you at an okay place to take a break then if you're moving to a new document?
MR. SLATER: Yeah. Let's go off the record.
THE REPORTER: Okay.
THE VIDEOGRAPHER: We're going off the record at 10:45.
[A brief recess was taken.]

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THE VIDEOGRAPHER: We are back on the record at 10:59 AM.
BY MR. SLATER:
Q. So looking now -- I'm going to skip over Exhibit B for a second, and we'll go to Exhibit C of your report.
A. Yes.
Q. This just lists your fee schedule, and those are the fees that you are charging in this matter?
A. Yes.
Q. So $750 an hour for your report, deposition preparation, for your deposition, for your trial preparation, and then $7,500 a day if you actually testify at trial?
A. Yes.
Q. Let's look at Exhibit D if we could. And for -- and just for the record, we should probably make sure that we mark the entire report with all of the attachments and exhibits as one exhibit.
MR. SLATER: I think, Chris, you might have marked something else as a separate exhibit. It's fine if you did. Like the CV might have been a different-numbered exhibit. But let's also have a

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comprehensive version of the August 27 report with all the attachments and exhibits. That's just for everybody's --

MR. GEDDIS: -- put together as one document, but I can --

MR. SLATER: We'll talk about it -- I want it all as one document. We don't want have to break them up.

MR. INSOGNA: And which number would that be, just so that I have it?

MR. SLATER: Well, we've already marked the report as Exhibit 7, so that should be the report with all the attachments and exhibits. I think, Chris, you might have marked Exhibit 8 as the CV separately also?

MR. GEDDIS: 8 is the CV, then 9 was the Exhibit C, and then Exhibit D I marked as 10.

MR. SLATER: Okay. It's fine. There's no harm in doing that. Okay.

[Exhibit 8 marked for identification.]

[Exhibit 9 marked for identification.]

[Exhibit 10 marked for identification.]

BY MR. SLATER:

Q. Looking now at Exhibit D, Doctor. This is

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a listing of your primary testimony, and it should be your prior testimony last four years.

Did you compile this list?

A. Yes.

Q. And you confirmed that this was an accurate list, all-encompassing?

A. Yes.

Q. Do any of these cases listed here -- well, let me ask you this in general. Are these cases all cases in which you testified as an expert in a medical malpractice case?

A. All except for one, I think.

Q. Which is the one exception?

A. The Deposition Number 7, Gross verse BNSF.

Q. Number 7, you said; correct?

A. On my list here, yes.

Q. What was the subject matter of that case, the Gross versus BNSF case?

A. This was -- or it's an ongoing case of a patient with colorectal cancer and exposure to asbestos and causation.

Q. And are you the expert for the lawyer -- rephrase. Are you the expert for the plaintiff, meaning the person with the cancer, or are you the

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expert or an expert for the defendant, the manufacturer of the asbestos?

A. The plaintiff.

Q. So you've offered the opinion in that case that that plaintiff's colorectal cancer was caused by asbestos?

A. Contributed -- asbestos contributed to cause, yes.

Q. Do you have the deposition transcript that you -- from the deposition you gave in October of 2019?

A. Yes, we can get it, I think.

Q. Do you have the other deposition transcripts for the other depositions listed?

A. I don't have them here, but I could get them if necessary.

Q. In the deposition in the Gross versus BNSF case, did you offer any opinions about alternative potential causes of the person's colorectal cancer?

A. Yes.

Q. Did the subject of nitrosamines come up at all in that case?

A. No. Not that I recall.

Q. In the cases you -- rephrase. You testified the balance of the cases listed here under

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trial and deposition are medical malpractice cases; correct?

A. I think all the other ones are that.

Q. In those cases, are you an expert for the plaintiff, for the defense, or is there a mix?

A. There's a mix.

Q. Is there any sort of a balance one way or the other where you'd say most of them are for one side or the other? I'm just trying to save walking through them all.

A. Yeah, usually when I'm asked that, in general it's about two-thirds to 70 percent plaintiff, and the remainder defendant.

Q. To your knowledge, has there ever been a ruling by any court as to the -- your qualifications or whether you could provide any sort of testimony that found either you weren't qualified or you couldn't provide testimony -- anything like that?

A. No.

Q. How would you define your profession in terms of what you do? What would you describe yourself as?

A. I am a medical oncologist that works at an academic center. I subspecialize in GI cancers and I

direct the GI oncology program at the University of Chicago, and involved in my roles there, which are multiple different aspects, includes patient care, clinical care of patients that have GI cancers for the most part, but occasionally all cancers, because I do inpatient rounds on sick patients that get admitted with various cancers.

I do research -- clinical trial research, laboratory research, something called translational research, which translates findings in the laboratory to clinical research and vice versa, findings from the clinical care of patients back to laboratory questions.

I teach along the way on various aspects on clinical care to, as we talked about earlier, medical students, residents, fellows, and also teaching from a research perspective in terms of volunteers and students that come through my research lab and clinical trial research endeavors.

I oversee as the GI oncology program -- that's in my report there -- the clinical and the clinical research program for GI cancers at the university, which entails a number of GI medical oncologists -- like we talked about Blase Polite, who is one of them -- and there are others, six at the

moment -- as well as research nurses, clinical nurses, clinical research staff, and overseeing that operation.

Also in the umbrella is we have satellite sites at the University of Chicago that are in various places in the Chicagoland area that are part of us and that see patients at those sites, but I oversee the clinical research at those programs as well, and even patients come back and forth from those centers to ours for opinions, et cetera.

In addition to that and part of all of that is writing grants to support clinical research questions. We talked about in my CV writing publications, writing commentaries, and in addition to that, other extramural things like we talked about and serving as an editor of journals, reviewing journals to provide back to the scientific community that's not actually -- for example, all those ad hoc reviews aren't paid for per se. They're just -- part of our scientific community is to peer review each other's work.

So in a nutshell is all of those things that I do as part of my academic position at the University of Chicago.

Q. In reading through your background, my

sense was that your focus of your professional work is on the treatment of cancer but with a specialization and focus on gastrointestinal cancers and trying to develop better ways to treat cancer.

Is that a fair understanding in terms of what your main focus is?

A. That --

MR. INSOGNA: Object to form. You can answer.

A. That's the primary intent of my research agenda, is in the treatment of patients with various GI cancers, yes.

BY MR. SLATER:

Q. Do you consider yourself to be a toxicologist?

A. I do not.

Q. Do you consider yourself to be an expert in toxicology?

A. I do not.

Q. Do you consider yourself to be an epidemiologist?

A. I do not.

Q. Do you hold yourself out as an expert in epidemiology?

MR. INSOGNA: Form.

A. I do not.

BY MR. SLATER:

Q. Am I correct that you do not consider yourself to be or hold yourself out as an expert in organic chemistry?

A. I do not.

Q. Do you consider yourself to be an expert in the field of risk assessment?

MR. INSOGNA: Object to form.

A. I guess it depends on -- can you clarify in maybe a more detailed question?

BY MR. SLATER:

Q. Risk assessment in the context of somebody who would evaluate whether or to what extent a certain exposure to a certain either chemical or other type of environmental exposure would cause a disease -- for example, cancer -- based on certain levels of exposure for certain durations.

Is that something that you do?

A. I do not.

Q. So you don't consider yourself to be an expert in that field; correct?

MR. INSOGNA: Form.

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A. Correct.
BY MR. SLATER:
Q. And I didn't see any such calculations or analysis, but did you perform any risk assessment calculations along the lines of what I just described to you in this case, in your work as an expert in this case?
MR. INSOGNA: Object to form.
A. Other than what's written in my report in terms of the -- for the most part rebutting some of the articles that were brought up by expert plaintiffs in terms of pointing out certain aspects that I thought were flawed or the limitations of the studies, and -- other than that, I didn't do any other things outside of this report.
BY MR. SLATER:
Q. And what I'm getting at is, did you independently do a risk assessment analysis where you calculated doses and duration of use of the valsartan pills at issue and do a calculation of what the risk level would have been to the various people who might have taken the pills?
MR. INSOGNA: Object to form.
A. I did a qualitative assessment of the

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topic, and after reviewing all of the expert -- plaintiff expert reports and the literature on my review, and I provided my opinion based on that review.
But I didn't do -- because it was my understanding that there was a toxicologist who would be performing more detailed -- a response to that question -- and so I touched on, as I mentioned earlier, some of the papers and opinions in terms of pointing out limitations, because ultimately I'm not a toxicologist or an epidemiologist, as you've pointed out. I am a scientist and I can read scientific literature and I can provide an opinion based on the data that I reviewed.
BY MR. SLATER:
Q. Did you do anything to independently either verify the calculations or the models or the conclusions found in those reports that you were commenting on?
A. I didn't -- sorry.
MR. INSOGNA: Object to form. Sorry.
A. I didn't independently do calculations outside of what I've already shown in my own report.
BY MR. SLATER:
Q. Well, that's what I'm trying to

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understand. I have your report, and I don't see any reference to you doing any independent risk assessment or calculations, so I just want to make sure I didn't miss that, that there's nowhere where you actually say you did a risk assessment or did a calculation or came up with the numbers as opposed to just commenting on the numbers provided by others?
A. Right --
MR. INSOGNA: Object to form. Vague, compound.
A. I was commenting on certain calculations and providing my own calculations. Sometimes they required calculations.
BY MR. SLATER:
Q. With regard to this area, this risk assessment toxicology area we're talking about, what did you do to ensure that you had seen each of the important sources of information? Because you said you looked at various literature. What did you do to make sure that you had seen everything that was significant?
A. I reviewed all of the plaintiff expert reports which they were relying on for the opinion, and from there I did my independent review of the topic and -- which includes a lot of the things that I

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included in my report -- and ultimately I was not performing a comprehensive detailed analysis of each of those questions.
I was -- and I think I pointed out in my report that I felt compelled to point out the ones that were brought forth by plaintiff experts because that's what they were relying on -- point out their limitations.
Q. So if I understand correctly, in terms of what the plaintiffs' experts opinions were, you saw yourself as providing basically rebuttal to what they said, as opposed to providing your own independent analysis from scratch?
Do I understand that correctly?
MR. INSOGNA: Object to form. Misstates testimony.
A. Because I'm not an epidemiologist or a toxicologist and my understanding was that there would be experts providing a more detailed and comprehensive response, I focused on pertinent to these particular topics as I mentioned earlier, the reports and the papers and the opinions that were brought forth by the plaintiff experts, presuming that all of the ones that -- all of the topics and papers that they were

using in favor of their arguments would be comprehensive. They wouldn't exclude ones that they thought were important to their opinion. So I focused on the ones that they brought forth.

And this is because -- I think I should sort of establish this -- is that whenever we have a scientific question and you have a proposed hypothesis, the null hypothesis is that it's negative, that there's, say in this case, no association, and that you have to show evidence to reject that null hypothesis and to accept the alternative.

And so if I'm reviewing it from the perspective that I'm looking at the data that have been provided to me to try and reject the null hypothesis and accept the alternative, I was looking at the data that was being brought forth to make that assessment, and those articles are the ones that are in the plaintiff experts' reports, so I focused on those to address those to see if I agreed or not with that opinion.

BY MR. SLATER:

Q. So if I understand correctly, you didn't independently research these issues; you looked at what the plaintiff experts had referred to, and those

materials were provided to you by counsel, and that's what you reviewed; correct?

MR. INSOGNA: Object to form.

A. That's where I started, with those articles, and I did an independent review, and there are articles in my report, for example, that they do not reference. I looked outside of their reports, but it was all focused on that question based on the original articles that the plaintiff experts used with --

BY MR. SLATER:

Q. You mentioned -- I'm sorry. Go ahead.

A. I was going to say, we're talking about the toxicology and the epidemiology question.

Q. Right. In terms of the level of rigor that you follow in your methodology when you, for example, publish something yourself or review it -- review something else somebody else wants to publish -- let me rephrase.

With regard to the epidemiology and toxicology opinions, from what I'm hearing, you didn't follow the same sort of process you would have followed if you were actually authoring original research or an original paper; correct?

MR. INSOGNA: Object to form.

A. No, I followed what I normally would do, which is start with a question, and whatever data I have to start with it, and then perform a more extensive literature search on the topic.

BY MR. SLATER:

Q. Is it your testimony that you reviewed in its entirety every single report written by the plaintiff experts and every single piece of literature that was referenced by all the plaintiff experts?

MR. INSOGNA: Object to form.

A. Only the ones that are in my reliance list are the ones that I relied on to make my opinion. So the answer is no, I didn't look at every -- look at every reference in great detail from the expert plaintiffs. But I looked at what I thought were their -- the articles that they were putting most of the emphasis of their opinions on, that they relied on heavily.

BY MR. SLATER:

Q. Part of your methodology is to review those source materials which were most significant? That was what you endeavored to do; correct? Let me ask it differently.

In terms of your method -- in terms of a -- rephrase. In terms of a scientific methodology, you were reviewing various materials -- literature, for example -- you wanted to make sure that you saw that literature which was most significant with regard to the questions you were trying to answer; right?

A. Yes.

Q. And if it turns out that you didn't review or consider something that was significant, that could potentially undercut the ultimate opinion; correct?

MR. INSOGNA: Object to form.

A. If there was an article that was pivotal or instrumental for the opinion to reject the null hypothesis, and accept the alternative hypothesis and I didn't see that, then that would be -- that would not be good.

BY MR. SLATER:

Q. In your report was it important for you to accurately characterize the findings in the studies that you discussed?

A. Yes, that would be an important thing to do -- strive to do.

Q. For example, in your peer review or editorial work, if you were to find or be told that

somebody said something in a proposed article that mischaracterized a source of information, that would be a problem and that would have to be fixed or the article would have to be withdrawn; right?

MR. INSOGNA: Object to form.

BY MR. SLATER:

Q. If it was something of significance?

A. There's -- if something found after the fact that's of significance, then articles can be edited or amended or retracted.

Q. Did you think that it was important for you to independent verify that each of the statements you made characterizing the findings in the articles you discussed were accurate?

A. Yes. That was what I would strive to do when I wrote my report -- ensure that things are accurate.

Q. You talked earlier about your work regarding research and actually being involved in the process to vet proposed research; correct?

A. Yes.

Q. We talked about that a little earlier?

A. Yes.

Q. And my understanding is none of the

research that you've either personally participated in or had a responsibility to review at some level has -- none of that has addressed nitrosamines or the potential risks to humans of nitrosamines; right?

A. Right.

Q. For example, there's no study that you've either been involved in or had presented to you as a proposed study where NDMA would be given to human beings to see what the effect would be on the human beings?

Has there ever been any such study like that you've been involved in?

A. No.

Q. If somebody walked into your office tomorrow morning and said, "I want to do a study where I'm going to give NDMA to humans and we're going to have a control group that's not going to get NDMA," do you think that has a chance to pass muster with the IRB?

A. I wouldn't be involved in such a study in my capacity in what I do from a research perspective because I'm more involved in treating cancer, so that wouldn't happen.

Q. Well, based on what you know about NDMA

and the reading you've done, you would agree with me that there's no IRB in the country that would agree to let that study go forward, because it would be unethical; right?

A. I don't know the details of the study that you're proposing, so I can't comment.

Q. All right, here's the study. We're going to get the valsartan pills that were manufactured by ZHP with the levels of NDMA that you've commented on in your report and we're going to give those pills to humans for five years every day, and we're going to have another set of people that's going to take valsartan that we know has no contamination risk at all, and we're going to see how those people do over the next 30 years.

Is that an ethical study?

MR. INSOGNA: Object to form.

A. Are they randomized?

BY MR. SLATER:

Q. Either way, whether they're randomized or not, people are going to get those pills that ZHP produced and they're going to take them for five years with those contamination levels of NDMA.

Is that an ethical study that could be

approved?

A. I don't know.

Q. In all of the research you've done, in all the reading you've done since you were first contacted in this case back in March of this year, have you seen any study where human beings were deliberately given NDMA at the levels found -- and I'll use, for example, at the levels found in the ZHP-manufactured valsartan.

Have you seen any study where that was deliberately done?

A. I have not seen any studies where NDMA was given deliberately in a randomized fashion, but I've seen one prospective randomized study that gave ranitidine, which putatively degrades or is activated to have NDMA endogenously after taking it to patients or not and following certain parameters. I think the primary end point was excretion of NDMA in the urine and changes with and without.

That would be the closest thing that would be a prospective study that evaluated that -- something like known exposures to something that putatively causes something, to address the question in a scientific manner.

Q. It was your understanding that the

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ranitidine study was conducted with the intent of exposing people to NDMA to see what it would -- how it would affect them?

MR. INSOGNA: Objection.

A. It's been a while since I read that paper, but it was intended to evaluate levels of excretion of NDMA and changes with or without ranitidine.

BY MR. SLATER:

Q. Is that the study that had to be withdrawn from the literature?

A. Not that I'm aware of. It was published in JAMA here. And that obviously wasn't determined to be unethical, because it was conducted and published.

Q. Where was that study done?

A. I don't know. I'd have to look up the paper again.

Q. Is the paper listed in your report?

A. No. You asked me if I knew of a study that did something like that, so that's why I'm telling you.

Q. No, that's fine. That was what I asked you. It was a new question.

Let's go now to Exhibit B to your report.

A. Okay.

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Q. Exhibit B to your report of August 27, 2021, is titled amended list of materials considered.

Do you see that?

A. Yes.

MR. SLATER: And Chris, let's mark as an exhibit separately the updated amended list of materials that we were provided with the production. Let's mark that as Exhibit -- I don't know what number we're up to. Are we now up to Exhibit 11 or 12?

MR. GEDDIS: 11. It's 11.

THE REPORTER: So this is going to be 12, Chris?

MR. GEDDIS: No, this is going to be Exhibit 11.

THE REPORTER: Okay. Very good.

[Exhibit 11 marked for identification.]

BY MR. SLATER:

Q. Doctor, what I'm trying to understand -- well, rephrase. Looking now at the Exhibit B to your August 27 report, is this intended to be comprehensive of everything you reviewed as part of your analysis of the questions that you answered in your report?

MR. INSOGNA: Object to form. Adam, are you asking about the update that came through in the

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file transfer this week, or are you asking about the August 27th?

MR. SLATER: I'm asking about the August 27th, but it could apply to either because I'm just asking about the purpose of the list. So the purpose would be the same, I would assume, regardless of which version it is. But let me ask the question again.

BY MR. SLATER:

Q. This amended list of materials considered which is attached as Exhibit B to your August 27 report -- what is that supposed to convey? What is that document?

A. This lists all of the documents that I reviewed that were pertinent for me to either include in my report or had some contribution to formulating my opinion.

Q. The exhibit we just marked as Exhibit 11 was provided to us when your files were provided to us.

To your knowledge, was that an updated version of this amended list of materials considered?

A. I think so.

Q. Do you know what was edited and why in the most recent version, which is Exhibit 11?

A. I don't know offhand.

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Q. Was there anything that you had located or identified as having not been included that should be so that you said, "I need to make sure this gets included"?

A. There may have been a paper, but maybe -- forget the name of the author -- but there was one paper about nonlinear estimations of dosing. Patrick I think is the name of the author.

Q. Who?

A. I think it's -- I could be wrong. I can get the name if you give me a second. It's Gerald. Excuse me.

Q. Looking now -- well, let me ask you this. Do you have Exhibit 11, the most updated amended list of materials, available to you?

A. I have a lot of them and we're trying to determine which one's the most recent one. This is the most recent one. So yes.

Q. Okay, great. I'm going to use that as the exhibit we're going to talk about now, because it's the most up-to-date amended list of materials we were provided before the deposition. Okay?

A. Okay.

Q. Looking at the first category, MDL

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pleadings and general documents, did you rely on any of those documents in forming your opinions in this case?
MR. INSOGNA: Object to form. Vague.
A. No, not really.
BY MR. SLATER:
Q. Did you read each of those documents?
A. Yes. I've looked through all of these documents, as I mentioned at the very beginning, some in more detail than others, though, that I put more emphasis on than others.
Q. When you say you looked through a document, I take that to mean that you may have skimmed it or jumped around to get a gist of a document as opposed to reading an entire document.
Do you make the same distinction when you say you looked at a document versus read the entire document?
A. Yes, sometimes I would skim through it, and other times I would really focus and sometimes read it five times, like a specific article, for example.
Q. So if I understand the MDL pleadings in general documents category, you looked through those documents but didn't rely on anything in those documents to form your opinions; is that correct?

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MR. INSOGNA: Object to form. Vague. Mischaracterizes.
A. I think some of those would have had the original cancer types listed, for example, that are part of the litigation, so of course I focused on those because that's what I was trying to focus on in my report.
BY MR. SLATER:
Q. So your answer is, with regard to that category of documents, the listing of cancers that were at issue was informative to you of what you were going to be addressing in your report? Do I understand that?
A. As an example --
MR. INSOGNA: Objection.
A. As an example to what I used those initial documents for.
BY MR. SLATER:
Q. Is there anything else that you used those initial documents for, the MDL pleadings and general documents -- that list right there?
A. Get an understanding of what the whole question was at hand.
Q. Did you rely on that in forming your opinions?

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A. It served as the basis of the starting point of what was happening.
Q. Anything else that you relied on in those documents to form your opinions?
MR. INSOGNA: Object to form.
A. I would have to go back and look to see exactly what's in them again, but -- I can think of at the moment.
BY MR. SLATER:
Q. There's a list of expert reports with exhibits. Did you read each of those expert reports cover to cover?
A. Yes.
Q. Did you rely on those expert reports or any parts of them in forming your own opinions?
MR. INSOGNA: Object to form. Vague.
A. As we talked about earlier, I used those reports as a starting point of what the argument was in terms of the opinion to reject the null hypothesis and accept the alternative hypothesis. So those were the reports that -- where the substance of that opinion lied.
BY MR. SLATER:
Q. Did you see anything in those reports that

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you found to be accurate with regard to the question that you were looking at, meaning did you look at any of the expert reports from the plaintiff experts and say, "I agree with that. That's a good point"?
MR. INSOGNA: Object to form. Vague, compound.
A. If the question is, was the report 100 percent inaccurate, then the answer to that is no -- every topic and every opinion stated there.
BY MR. SLATER:
Q. Do you agree with me it was important for you in writing your report to focus both on those things that were supportive of the position that you were taking, as opposed -- as well as that information which was contrary to the position that you were taking?
A. That's how science works, yes. You have to look at all the data on a pertinent question and make an assessment if there is enough information there that would lead you to reject null hypothesis and accept the alternative hypothesis.
Q. So for example, if there was an article that you found to be important in forming your opinions, was it also important for you in your report

to talk about those aspects of that article that supported your opinion as well as those parts of the article that would cut against your opinion and be supportive of the plaintiff position?

Did you feel it was important to address both sides of that coin in your report?

MR. INSOGNA: Object to form.

A. Yes, which I strive to do, is to show all the evidence, the discussion points around them, and an overall opinion as to where my -- where the data lie in terms of whether or not it's enough to sway away from the null hypothesis or not.

So it's not often that you would see all data point to one thing. The way science works is that there are different outcomes with different studies, and ultimately you have to look at the data as a whole in terms of whether or not there's consistency with the findings, what type of evidence we're talking about, because I think as we'll get to along the way here, different studies are different and contribute different things to the understanding of the question at hand and have different emphasis and weight in terms of ultimately how you're going to make your final opinion.

So yes, though, you have to look at all available data that's there and then, taking all those points into account, come up with a decision whether or not you think there's enough to be swayed away from the null hypothesis. That's how science works. You don't ignore data.

BY MR. SLATER:

Q. Not only were you obligated to look at all of the data and look at the data on both sides of the question, but you would agree with me you also in your report, if you were going to cite an article, needed to talk about the information that was both pro and con to the position you were taking in order to be evenhanded; correct?

MR. INSOGNA: Object to form. Argumentative.

A. Which is why I've referenced all of the articles that the expert plaintiffs rely on for their opinion.

BY MR. SLATER:

Q. It's a little bit of a different question. In writing your report where you evaluated the literature and the studies, was it important for you to make sure that if you were going to point out aspects

of the data or the findings that were supportive of your position that you also make sure you pointed out the data and findings that was not supportive of your position if there was such information?

MR. INSOGNA: Object to form.

A. I think I answered that in the sense that all the data that was not ultimately in line with my opinion is referenced there, because that was where I started, was where the plaintiff experts were using that.

And I think it should be stated that the way science works is that you don't have to disprove the null hypothesis; you have to prove the alternative hypothesis in order to reject the null hypothesis. The onus is not on me to prove that it's not true. I'm looking at the data that's being provided to me to try and sway me away from that.

BY MR. SLATER:

Q. My question is not -- well, again -- rephrase. Again, what I'm -- rephrase. What I'm asking you is, when you wrote your report and discussed a particular study, in terms of a valid methodology of writing this type of a report, you needed to reflect in your report the information that was supportive of your

position but also to be evenhanded to discuss in your report the data that wasn't?

I'm not saying just citing the article, but actually discussing with substance, "They say this. That was important to me. It supports this. They also say this, though, and I do have to acknowledge that could go the other way."

Should you have been evenhanded like that?

MR. INSOGNA: Object to form. Argumentative.

A. And the answer to that is yes, and I mean, I can go through and find examples, but as an example that comes to mind, I pointed out limitations of articles that I was relying on that ultimately don't show an association but that there were limitations to the study, like there are -- in all studies there are some limitation. So that's an example of showing both sides, and from a scientific perspective that's normal and natural to do something like that.

BY MR. SLATER:

Q. From a scientific perspective, it would never be acceptable to mischaracterize the data in a study and describe it in such a way that it spins the article and the findings one way or the other; right?

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MR. INSOGNA: Object to form.
A. Not in an intentional malignant way. That's an opinion that one takes out of the data and that's their opinion based on how it's interpreted, and -- for example, some studies provide data and can -- some physicians interpret it differently than others, and it's different interpretation of the data.
BY MR. SLATER:
Q. It certainly would never be acceptable to characterize the data and findings in the study in such a way that doesn't accurately reflect what the article actually says; right?
MR. INSOGNA: Same objection.
A. Sometimes, for example, I don't agree with every point or conclusion that is mentioned in an article, so for me to opine on that I think is part of the scientific method.
Sometimes statements in articles are speculative or trying to explain a phenomenon, but that doesn't make the statement in an article a gold standard, and that's just the author's interpretation or thoughts, but it doesn't make it the -- it's not infallible, if that's the question. So I can review the same dataset and provide my own opinions on that

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data.
BY MR. SLATER:
Q. With regard to objective data points, it would never be acceptable to mischaracterize those objective data points; correct?
A. No, if there were -- if it was about a number or something that was a data point and it was misrepresented, that could happen, but that's not what I'm talking about. That would be -- that's not how science works. You can't change the dataset.
Q. If there's objectively-reported data in the study that you're talking about, it would not be scientifically-acceptable to talk in your report about that objective data that's supportive of your position while not referencing and discussing on the other hand other objective data in the study if it actually is supportive of the opposite position; right?
You have to be evenhanded in what you discuss in your report; right?
MR. INSOGNA: Object to form. Argumentative, mischaracterizes.
A. You would strive to do that, and I'm not sure what example -- because maybe it's an example that we should have the details of, because it's a little

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bit vague what we're talking about here. Like are these two data points? Is one a primary end point and others are secondary end points? Because that is an important thing to consider.
But I'm not sure what you're asking, but of course, if it's a data point, then it should not be mischaracterized or changed -- the number changed, for example, intentionally.
BY MR. SLATER:
Q. We talked a little bit earlier about the toxicology and epidemiology aspects of your analysis. Remember that?
A. Yes.
Q. And I think you told me that you knew that there were other people that were actual toxicologists and epidemiologists who were going to address that in a thorough manner, so you didn't feel like you needed to get into that kind of depth because there were other people analyzing that.
Do I understand that correctly?
MR. INSOGNA: Object to form. Mischaracterizes the testimony.
A. I was informed that there would be specific experts asking those questions from that

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perspective, and so -- and I'm not a toxicologist or an epidemiologist, but at the same time I think I mentioned earlier I can read papers, scientific papers, and evaluate their strengths and limitations and evaluate them in terms of my ability to formalize an opinion on a given question that is a scientific question.
BY MR. SLATER:
Q. Had you authored -- go ahead. I'm sorry.
A. I was going to say, the language of science is universal in terms of understanding how to apply scientific method -- different disciplines of science like epidemiology, biology, chemistry, epidemiology, toxicology -- but the methods with which one tests hypotheses, as we've been alluding to all along the way here, is the same. So I can weigh data in the same manner.
Q. In terms of the -- what you just referred to as weighing the data, would you agree with me that the toxicologists and epidemiologists in this case did that in a more rigorous manner than you did because that's their specialty?
MR. INSOGNA: Object to form.
A. They did it in their manner from the way

they do it in their discipline, yes. I looked at it, as I mentioned earlier and in my report, after reviewing the plaintiff experts' reports and seeing the papers that they were relying on for their opinion and evaluating those papers and pointing out limitations and strengths from those papers and how that played a role into my opinion that I was asked to give, which one of them was the question at hand -- is, is there an association with cancer risk with the trace impurities that were found in these agents or not based on the available evidence to date?

BY MR. SLATER:

Q. You just used the word trace impurities. How do you define that term?

A. How do I define it? I --

Q. Yeah. Why did you use the word trace? What does that mean?

A. Because they're small -- like they're very small amounts in each of the -- in the pills. I mean, that's what they were referred to in many of the reports and in the FDA reports that I read and referenced.

Q. The amounts of NDMA in the various pills varied depending on the manufacturer.

Are you aware of that?

A. Yes.

Q. Are you saying that all of those levels right up to the highest level seen are all trace amounts and very small?

A. Yes.

Q. What's your frame of -- what's your basis for that opinion?

A. All in my report in terms of looking at our daily exposures to NDMA based on exogenous and what's endogenous, the estimates of endogenous -- the levels that are found in these pills are minuscule compared to that, so that's what the word trace means to me, is that there are small amounts.

Many of the lots there was nothing detected, below the limit of detection, and all the levels are relatively low compared to the known levels that we are exposed to on a daily basis based on the references and studies that I pointed out in my report and after the fact seeing that in many of the other expert reports.

Q. Did you see any levels of NDMA in any of the pills that exceeded the levels that one may be exposed to through just background exposure?

MR. INSOGNA: Object to form. Vague.

A. I don't have them in front of me, but I know that the answer to that is no. The levels are far lower.

BY MR. SLATER:

Q. And that's based on, which we're going to get to later, your understanding about how much exogenous or endogenous NDMA one may be exposed in everyday life?

A. Right. That's right.

Q. On the first page of this list of materials considered, there's a heading deposition transcripts with exhibits.

Did you read each of those deposition transcripts in their entirety?

A. Yes. Yes.

Q. Did you read all the exhibits in their entirety?

A. I looked at as many as I could. I didn't read them all in detail, no. I focused more on the deposition itself. Some of the -- what did you call them -- attachments? Is that what they're called -- the attachments?

Q. To the report?

A. Yeah.

Q. Exhibits?

A. Exhibits. Excuse me. Many of them are articles that were -- I already read because they were part of the original review of generating my own report, but yes. Did I read through everyone's CV entirely? No.

Q. One of the materials listed here is the transcript of Raphael Nudelman deposition.

Who is that?

A. That is a deposition, as I looked at that name, that I read right near the beginning. You can see the date there. I think it was in April. So I'd have to look at it again to remind and refresh my memory what it was.

Q. As you sit here now, you're not sure who Raphael Nudelman is?

A. I can't remember --

Q. One of the things you said -- go ahead. I'm sorry.

A. I was going to say, I haven't reviewed that deposition recently.

Q. One of the things you told me earlier was that these materials were provided to you by defense

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counsel; correct?
MR. INSOGNA: Object to form. Misstates testimony.
A. Some of them.
BY MR. SLATER:
Q. Well, I guess the transcript will speak for itself. With regard to the -- new question. With regard to the materials that defense counsel provided to you, did you expect that defense counsel would give you materials that would not only be supportive of the position that you were going to take, but also those materials that could cut against the position you were going to take?
MR. INSOGNA: Object to form. Mischaracterizes testimony.
A. In terms of actual literature, I didn't expect them to provide me with anything, really. I would do my own independent research. In terms of depositions and some of these other legal documents, then the answer is yes. I would be expecting to receive all the pertinent records for balanced decision and opinion.
BY MR. SLATER:
Q. And that's the key, is that you --

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ultimately if you're doing something that's scientifically appropriate in terms of methodologies, to have a balanced dataset; right?
MR. INSOGNA: Object to form.
BY MR. SLATER:
Q. Meaning the data on both sides of the question; right?
MR. INSOGNA: Same objection.
A. Yeah, I think we've alluded to that particular question about data, as opposed to like a deposition that happened previously.
BY MR. SLATER:
Q. For exam -- rephrase. You relied on defense counsel to get you the pertinent legal documents -- things like depositions, things like internal corporate documents; correct?
A. Yes.
Q. And if there were such documents that existed that would support the position that you are contrary to, the position -- well, rephrase.
If there were such documents that supported the position that NDMA and NDEA can cause cancer in humans, you would have wanted to see that; right?

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MR. INSOGNA: Object to form. Assumes facts. Argumentative.
A. Yes, I would like to see all the documents that were known on either side of the opinion.
BY MR. SLATER:
Q. For example, if there were internal documents from Teva, for example, in which people at Teva were recognizing the danger to humans of NDMA and NDEA in the Teva valsartan, you would have wanted to see that so you could take it into account in your analysis; right?
MR. INSOGNA: Object to form. Assumes facts, argumentative.
A. We're talking about discussions amongst employees at the company?
BY MR. SLATER:
Q. No, we're talking about -- well, it would include that -- let me rephrase. It would include that. It could also include an analysis of this particular question, like when the company found out there was NDMA in its valsartan, their internal analysis of the risk to humans.
You'd want to see that; right?
MR. INSOGNA: Same objection.

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A. I would like to see all evidence as much as possible, yes. The more data -- I wouldn't exclude data. Whether it would be important in my decision is another question, but if there was evidence or some sort of data, then of course, you have to -- what is available, you review and assess.
BY MR. SLATER:
Q. For example, if there was deposition testimony or internal documents from one of the manufacturers in which it was acknowledged that NDMA or NDEA could cause cancer in humans, that's something you certainly would have wanted to see; right?
MR. INSOGNA: Object to form. Assumes facts.
A. I would want to see that, yes. Would that have played a role in my decision, what they thought? Not necessarily.
BY MR. SLATER:
Q. What if the "they" was a toxicologist retained by one of the companies to analyze this exact question?
Would that have been important to you to see?
MR. INSOGNA: Same objection.

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A. If they had done an analysis, sure, I would like to see what they showed --
Q. What if it was the testimony of a corporate witness who was speaking for the company on that specific question of the risks of the NDMA and NDEA in the valsartan and that person acknowledged that there was a risk to humans of cancer?
Would you have wanted to see that?
MR. INSOGNA: Same objections.
A. Sure.
BY MR. SLATER:
Q. For example, if there were witnesses who testified for one or more of the manufacturers who agreed that NDMA and NDEA are probable human carcinogens, if they said that in sworn testimony speaking for the company, would you have wanted to see that in forming your opinions?
MR. INSOGNA: Same objections. Assumes facts. Do you have a document you want to show him, counsel?
BY MR. SLATER:
Q. Please answer.
MR. INSOGNA: You can answer.
A. Sure, I would like to see that, and I

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don't think what you just said would be anything different than what I just already said earlier, and that's been said by many experts, that it's acknowledged that it's a probable human carcinogen. It's not a definite human carcinogen.
So what you're telling me right now is not changing anything that we already know, but would I want to see the document? Of course.
BY MR. SLATER:
Q. And when you refer to the probable human carcinogen, that's the finding IARC made; right?
A. Right.
Q. And you don't disagree with IARC; right?
A. Well, I think we're going to get into it, but maybe this is a good time to say. IARC is telling us that those -- that NDMA and NDEA are probable human carcinogens, but that doesn't take into account the dose or the duration of the exposures to these agents and that they -- ultimately they're an extrapolation from animal models, from rat models, with a lot of limitations that are quite conservative.
But yes, I mean, I think we've established that IARC said that, and so this other document you're talking about so far from what you told me wouldn't

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change anything that we already know.
Q. Just so I make sure that it's clean for both of our benefit, you don't disagree with the finding by IARC that NDMA and NDEA are probable human carcinogens?
That statement in and of itself you don't disagree with; right?
MR. INSOGNA: Object to form. Asked and answered.
A. Yeah, I just answered that question. So yes, I don't think that I disagree with that, with the understanding I also mentioned, is that that doesn't take into account the dose and the duration, which I think is an important thing to consider here in this particular question.
BY MR. SLATER:
Q. Putting aside dose and duration, which would become relevant to determining whether a particular person claiming a particular cancer actually got cancer in whole or in part from the exposure to the NDMA in the valsartan pills --
I think that's what you're driving at; right?
A. No.

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MR. INSOGNA: Go ahead.
A. No, that's not -- I'm not talking about that at all. I'm just saying that because it's listed as a probable carcinogen is one thing, but do have to understand that all that's saying is that at some dose level and for some duration that it's probably carcinogenic in humans.
Again, it's only probably and not definitively because it hasn't been shown in humans to have that, yet it has in some animal models, at huge doses, by the way, and for long durations that are astronomically higher than what's in this case, which is why I called it trace exposure in this case.
BY MR. SLATER:
Q. Okay, I see where our disconnect is. I'll try to ask the question artfully. You -- rephrase.
You agree with IARC that NDMA and NDEA are probable human carcinogens, putting aside the dose or duration of use or exposure -- putting that aside, you don't disagree that those substances are probable human carcinogens; correct?
MR. INSOGNA: Form. Asked and answered.
A. If you're asking me to put those other considerations aside, then yes, officially the IARC

classifies these as 2A.
BY MR. SLATER:
Q. And you don't disagree with that; right?
A. No.
Q. Your answer was no?
A. No, I don't disagree with that.
Q. Sorry. Sometimes with the delay I get a click on my -- it's totally on my end. I just missed it. I'm sorry.
[Discussion off the record.]
BY MR. SLATER:
Q. Let's go back to the amended list of materials considered, the regulatory guidances and documents. First there's a heading that says publicly-available documents.
Do you see that?
A. Yes.
Q. Have you read or reviewed any of those materials before you were retained in this case?
A. No.
Q. In terms of forming your own opinions in this case, are you relying on the regulatory information to form your own scientific conclusion, or is this more background information on what occurred

and what the regulator said?
How do you mix that into your analysis? I want to understand how it fit into your methodology.
MR. INSOGNA: Object to form. Compound.
A. It was obviously background to understand the timeline of what happened and what the FDA's positions were along the way. I actually referenced a lot of their statements.
And so with your question about how to formulate my opinion, a lot of what they made mention and that I point out in my report does have some weight in terms of my understanding of things in terms of the risk, the risk assessment that they had made based on these putative exposures, et cetera. All of their statements did play a role into my opinion.
BY MR. SLATER:
Q. In that context, the FDA, for example, established acceptable -- what they called acceptable intake limits.
You're aware of that obviously; right?
A. Yes.
Q. You didn't do an independent assessment and form an opinion as to whether or not those figures the FDA adopted are reasonable or not; right?

A. I didn't do calculations to show what I would perceive as being an acceptable intake. I've read the toxicologists on both sides, and as I mentioned I think earlier, I added a paper that I found after from Fitzgerald, I think, about other ways of determining acceptable intakes.
And so I did take that into account and I think even in my report you can see where I discussed the acceptable intake from the FDA standpoint and some of the limitations of it.
Q. You didn't do an independent assessment of the intake levels for the FDA and form an opinion that those levels were unreasonable?
I didn't see that opinion in your report. I just want to make sure I didn't miss it.
MR. INSOGNA: Objection. Compound.
BY MR. SLATER:
Q. I'll ask it differently because counsel objected. He -- just like I have to be evenhanded, I have to assume I could ask a bad question every so often.
I didn't see an opinion in your report that you disagree with the acceptable intake levels established by the FDA.

There isn't such an opinion in your report? Am I correct?
A. I don't know verbatim what I put about that in my report, but if you want my opinion I can tell you right now, but I don't remember what the actual detail -- how I mention that or worded it in my report in terms of that particular threshold level.
Q. What I want to do is -- part of what I'm doing is you understand the purpose of your report obviously is to give us notice before your deposition of what your opinions are.
You know that; right?
A. Yes.
Q. So my goal is not to expand into a bunch of other things and ask you a bunch of things you didn't think about. My goal is to try to stay within your report because those are the opinions we've been told about.
You understand that; right?
A. Yes.
Q. In the report itself, I did not see an opinion where you said that the FDA acceptable intake levels are unreasonable for some reason and that different levels should have been adopted and here's

why. I didn't see such an analysis.
Did I miss it, or is it not there?
A. I don't think I did that analysis explicitly in the report.
Q. For purposes of your opinions, did you accept -- well, let me ask it this way.
You said that you've seen some studies where different people in some articles calculated different levels or different approaches to looking at acceptable levels, but putting that aside, you accepted the FDA levels for purposes of your analysis; is that correct?
MR. INSOGNA: Object to form. Misstates testimony.
A. Well, no. I mean, I think that that's why I was getting a little confused what you're asking -- is that I pointed out from the dietary studies, for example, the exogenous and endogenous known exposures that we were talking about earlier, which are way higher than this supposed acceptable rate that the FDA is saying, and I point that out here.
So intuitively that means implicitly that clearly it's lower than what we're always exposed to on an everyday basis, but also point out that it's a

conservative estimate that was extrapolated from a rat model in a linear fashion that was using doses that were really high doses compared to what we actually know are exposed to on a daily basis and also the question at hand in the trace impurities. So I did point that out in a number of places in my report.
BY MR. SLATER:
Q. You did not actually perform a risk assessment where you took into account all the various data points in the animal studies, the dietary studies, et cetera, and perform your own analysis and establish what would be an appropriate alternative acceptable intake level?
That's not something you did; right?
MR. INSOGNA: Object to form. Compound.
A. I didn't do that, no.
BY MR. SLATER:
Q. On Page 2 of this document we're looking at, there's a heading company documents produced, and those would have all been provided to you by counsel; correct?
A. Yes. Some of them I found on my own, like the FDA statements, as we talked about. But yeah, some of -- they were all provided by counsel.

Q. Well, I'm in the next section now, actually, so I want to make sure we're clear. On Page 2 there's a new heading, company documents produced.
Do you see that?
A. Oh. Sorry. I'm looking at materials considered at the top of that page, so now in the bottom, yes, those were definitely ones that were provided to me.
Q. And again, to the extent that defense counsel had in their possession company documents that one would objectively say, "Well, that actually supports the position that these substances could cause cancer in humans," you would have wanted to see those so you could take that into account; right?
MR. INSOGNA: Objection. Assumes facts.
A. I think I answered that I think all data are good to consider. Whether or not they would actually play a role any differently in an opinion is a different question, though -- until I saw the data.
BY MR. SLATER:
Q. Assume for this question that there is deposition testimony and documents you were not shown that an objective viewer would look at and say, "Well, that clearly supports the plaintiff's position in this

case that the NDMA and NDEA could cause cancer in humans at the dosages taken in the valsartan pills." I'd like you to assume that exists.
I'd also like you to assume it was not provided to you. If that's true, would you agree with me that subject to seeing that information, your opinions could change if you were to see that information because you don't have it available?
Would you agree with that?
MR. INSOGNA: Objection. Assumes facts, incomplete hypothetical, argumentative, misstates testimony.
A. I would have to see what it is that you're talking about to make an appropriate answer to that question.
BY MR. SLATER:
Q. Looking now at Page 4 of this document, the heading literature.
Is it your testimony that you read every one of these articles cover to cover?
A. No, I didn't read them all cover to cover.
Q. Just --
A. Some of them are skimming through, looking at abstracts, looking at main findings. Other of them,

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I did read cover to cover multiple times.
Q. And just to be clear and you could confirm this just so we have it for the record. This section headed literature starts on Page 4 and goes all the way to Page 39, about three-quarters of the way down the page; right?
A. Yes.
Q. If the counsel for the defense was aware of literature that objectively viewed would cut against the position that you've taken in your report, you would have wanted to be given that literature by defense counsel so you could take it into account in forming your opinions; correct?
MR. INSOGNA: Objection. Assumes facts. Argumentative. Incomplete hypothetical.
A. If I hadn't already found it and if it wasn't in the actual plaintiff experts' reports, which presumably such documents would be there and relied upon, then if everyone missed it except for defense counsel, sure, I would like to see it.
BY MR. SLATER:
Q. Well, this list of literature is the -- well, let me ask this question. Let me understand something. We'll take a step back.

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In the report you have references, numbered references?
A. Yes.
Q. And the purpose of that is so that if you said something in the report and you're specifically relying on a specific document or a specific study or piece of literature, you're telling us that's where this comes from; right?
A. Yes and no. Sometimes it's -- especially in the background sections of my report or the backgrounds of cancer where much of what I was saying is common knowledge in my field, but to provide some references in case somebody wanted to go and look at it, one or two token references on a topic, certainly not an exhaustive reference for each topic is in this report or there would a billion references here. And so yes and no.
Sometimes it's more of whoever's reading this can go and look more at detailed information from that discussion if they wanted to, which is a lot of how we do our references and publications.
And sometimes we have limit -- most of the time we have a limitation in terms of the number of references one can get included in a paper, and so I'm

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always in the mind frame from that sort of coming from that framework, is that I'm trying to be concise and not include every single topic and every single statement having heavily-referenced articles.
Q. In the course of your report you cited with specific reference numbers certain literature. If there's other literature in this list of literature that was not specifically referenced with a numerical reference number, does that mean that it's something you looked at for background but it's not something that you found to be so significant that you needed to specifically cite to it in the report?
MR. INSOGNA: Object to form.
A. Yes, like the example that came up earlier where one of the articles that I came across and I read, it wasn't as pertinent to my actual opinion. I had read it, but it wasn't something that I relied on or discussed, and that was that JAMA article; right?
But when you asked me about it, then, yeah, I know about it because I came across a lot of things as I was filtering through what I thought was necessary to formulate my opinion here.
BY MR. SLATER:
Q. So with regard to the items on this list

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of literature that are not specifically referenced in your report, again, that would be general background information as opposed to something that you thought was so important to your opinion that you needed to actually reference it specifically? Is that correct?
MR. INSOGNA: Object to form. Misstates testimony.
A. I'd have to look at the exact example you're looking at to be certain because sometimes maybe it did influence what I was thinking, but I didn't actually put the number here in the reference. But overall I think it would be safe to say that the things that are referenced here are the ones that are the emphasized reports that were relied upon for generating my opinion.
BY MR. SLATER:
Q. Looking now at Page 39 of this document, there's a heading that says records of bellwether plaintiffs. And I assume what that means is that you're been provided some of the records of some of the bellwether plaintiffs and you're evaluating specific causation in some cases as well.
Is that a fair assumption?
A. No, they were provided to me. I looked

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at -- this was a long time ago when they were first given to me back it looks like in April, and I was sort of told that these are -- just to have a full sort of file of this, but you're not -- we're not going to be doing specific patient cases at this point. So I didn't put a lot of emphasis on reading that to great detail.

Q. Am I correct you didn't rely on the records of bellwether plaintiffs, as you've listed those materials here in forming those opinions in this case?

A. Yeah, I didn't look at them or use those to make opinions here in this in any significant way.

Q. Could you go to Page 52, please? On Page 52 there's a heading postmarketing periodic safety reports.

Do you see that?

A. Yes.

Q. Why did you include those documents that come under that heading? What was the point of that?

A. I think as mentioned earlier, I think it's just to have a complete file to look at. As you were alluding to earlier, to have as much of the information available to evaluate along the way what was being

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documented.

Q. Did you ask for these documents, which as we can see in the subheadings are various ANDAs -- ANDA?

Did you ask for that, or was that just provided to you by counsel?

A. I can't remember.

Q. Did you rely on those documents in any specific way in forming your opinions in this report?

A. Not in a significant way. I looked at them. I think that they have limited utility in the questions that were being asked of me.

Q. I didn't see them cited for any proposition or to support any of your opinions. Right?

A. Yeah. Like I said, I think I just said that they had limited utility in forming my opinions.

Q. Looking at the Page 53, there's a heading that says miscellaneous.

A. Which page? Excuse me.

Q. Last page, Page 53.

A. Yes.

Q. It says miscellaneous.

A. Yes.

Q. The first section under miscellaneous is

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all plaintiff diagnosis and treatment report.

Do you know what that is?

A. I think that must be related a little bit to the other section that was about the actual patient, which I didn't look at in great detail.

Q. The next line says, "All plaintiff diagnosis and treatment report additional data."

Would that be the same answer?

A. Yes.

Q. The third line says, "All materials cited or referenced in my expert report and attachments."

Do you know why that's listed there?

A. Just to be explicit that all of the things in my report are here. Certainly -- in case one was missed, maybe to ensure that -- that would not be intentional.

Q. So that means if something was referenced in the actual body of the report but didn't find its way into this document, Exhibit B, you're saying I'm relying on it if it's stated in my report, but I didn't get it onto this list?

A. That's what that sounds like, yes.

Q. Or I read it? May not be relied on, but I read it; right?

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A. Sure. Yes.

Q. The last line here says, "This list includes items plaintiffs' experts relied upon. By so doing, defendants and this expert are not waiving any arguments or objections related to admissibility."

Do you know why that line was included?

MR. INSOGNA: Object to form.

A. I don't.

MR. SLATER: Counsel, this is probably another good break point, and it's 1:30 -- or 12:30 where you are. I don't know -- it's probably a decent point to break and eat if you want to eat. Want to go off the record and talk about it?

MR. INSOGNA: Yeah, we can go off the record and discuss it.

THE VIDEOGRAPHER: We're going off the record at 12:24 PM.

[A recess was taken.]

THE VIDEOGRAPHER: We are back on the record at 1:20 PM.

MR. SLATER: I just realized why I keep writing down the wrong time, because you keep telling the time Central Time.

BY MR. SLATER:

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Q. Okay. All right. I overlooked one thing I wanted to ask you about earlier, so let's just cover that, and then we'll go back into some other things.

Have you consult -- new question.

Have you consulted for pharmaceutical companies over the years?

A. Yes.

Q. When did you first start consulting for the pharmaceutical companies?

A. Probably around 10 years ago, 11 years ago, when I joined faculty at the University of Chicago.

Q. What do the consulting activities relate to? I'm not talking about grants for studies. I'm putting that to the side.

Other than any actual grants for studies, what does your consulting work for the pharmaceutical industry involve?

A. Most of the time it's advising in terms of novel therapeutic agents and how to develop them or where to develop them and looking at some of their data and giving opinions as to what the utility user is not in -- in the future of treating that cancer. That's -- most of that is consulting to that degree.

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Q. What else?

A. In a smaller subset, I've been asked to be a speaker for certain products, and I will -- I have done that, and I do that much less often, but -- and usually for therapeutic drugs that are for specific treatments for gastroesophageal cancer, which is my sub-subspecialty.

Q. Do you have an estimate of what you've been paid either annually or in total by the pharmaceutical industry for things like promotional or speaking, consulting, travel and lodging, reimbursements for food and beverage, all those things taken together? Do you have any estimate of what that's -- what those payments have been to you over the years?

A. Yeah, those are -- should be online through the open Sunshine Act policy.

Q. Do you have an understanding or an estimate of what those amounts have been that you've been paid?

MR. INSOGNA: (Inaudible.)

A. Yeah, I mean, I'd have to look back, but I can tell you probably over the years, as I have become more senior and involved, I get asked to do more

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things. And so looking over the years, it has probably gone up each year a little bit, but on average it's over the last 10 years maybe $20,000, $25,000 a year, roughly, as an estimate as to how much has been provided to me as honoraria for various consulting that I've done.

BY MR. SLATER:

Q. We did a little research and came up with some online information. As you said, it is available. And going backwards, the data I found showed payments of $37,000 approximately for the activities that we just talked about in 2020.

Does that sound correct?

A. Yeah, that sounds in line.

Q. And I have a number in 2019 of $41,611.60.

Does that sound correct?

A. Sounds like it could be correct.

Q. In 2018, I have the number of $59,127.48.

Does that sound correct?

A. Sounds like it's getting higher than average, but one thing I'll point out is that sometimes things like research funding to clinical trials gets into that database and inaccurately lists amounts that come to me directly.

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But regardless, it is probably, as I mentioned, on average -- over the last few years $25,000 as an average over the full 10 to 11 years. Some years more, some years less. More recent years --

Q. I can tell -- yeah, I can tell you that they break out -- this is the open payments website from the U.S. government, and they actually break out research funding as a separate category. So I'm just limiting it to the nonresearch funding category.

A. Right, and what I'm saying is that there has been occasion when I was looking at that and it didn't make sense and it wasn't accurate and I had to have them remove it in the past.

But regardless, I'm not sure about that either. It sounds like it's still within line of my actual activities with them as a consultant. So --

Q. So the number that we had left off with was for 2017, $78,534.93, and they count 82 payments that year.

Does that sound accurate?

A. 2018?

Q. 2017.

A. Yeah, that -- some of those, like you had already pointed out, are for travel. So I think in

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that year was the year that I went to Europe on a business flight. So more than like 15 percent of that is just from that one flight.

Q. The Dollars For Docs website, which gets its information, as you know, from the government data, for 2017 has your travel and lodging as $14,196; your promotional and speaking payments at $15,230; your consulting at $37,350; accredited training, $9,800; and then the food and beverages, $1,953.

Do those numbers sound accurate?

A. That sounds right.

Q. For 2018, the Dollars for Docs website had promotional and speaking as $37,933; consulting as $7,725; travel and lodging at $6,640; and food and beverage at $1,290.

Does that sound accurate?

A. On the surface, it sounds similar, yeah, to the previous year, and accurate.

Q. When there's reference in these documents to promotional speaking, does that mean when you're speaking on behalf of the company and they're paying you as a speaker?

A. It was what I was referring to earlier, where I'll speak on one of their products to a group of

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physicians, usually, or health care professionals on details of that product.

That usually is an FDA-approved product that has a topic of the actual studies that led to the FDA approvals and a balanced representation of the risks and benefits of that drug.

And so they're like viewed as a -- educational presentations to physicians in the community that aren't as aware of these new drugs that are coming through to bring awareness for them.

Q. They're viewed as educational, they're also viewed by the company as marketing events because they're hoping that the doctors you're speaking to will utilize the product that you're talking about; right?

MR. INSOGNA: Object to form.

A. They are commercial events from their perspective, and I think that's obviously why they do it, why I do it. I only do talks for drugs that I use and that I believe are beneficial to patients with cancer, and I view it as a way to communicate and meet new physicians and relate that information of that drug.

BY MR. SLATER:

Q. These speaking engagements -- they're

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arranged for and completely organized by the pharmaceutical company; right?

A. Not always. Sometimes they are through a third independent party and offer continuing medical education, for example. And so sometimes they are not organized by the company themselves.

Q. Well, the promotional speaking where the marketing department -- well, let me ask -- let me rephrase.

The promotional speaking wouldn't be continuing education; that would be promotional -- where you're promoting the product; right?

A. Yes, for ones that you're referring to, then they would be organized by the pharmaceutical company.

Q. And you would be interacting with people from the marketing department; right?

A. I believe so. They're commercial marketing, sales.

Q. They arrange for the doctors to attend and they bring them to the event; right?

A. Yes.

Q. And you certainly understand that the reason they're retaining you to speak is because

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they're hopeful that when you speak about their product that the doctors in attendance will choose to purchase the product or prescribe the product that you're speaking on, as opposed to competitors, for example; right?

MR. INSOGNA: Object to form. Calls for speculation.

BY MR. SLATER:

Q. You understand that's what the marketing people who hire you want to happen; right?

MR. INSOGNA: Object to form. Calls for speculation.

A. I think that that is true.

BY MR. SLATER:

Q. Now, let's go back to your report, if we could. And I think probably we should use the most recent version, the August 27, 2021, version.

A. Yes.

Q. So I'm going to walk through the report a little.

The first section is the biography and qualifications, and that's just an overview of your background; correct?

A. Yes.

Q. The second section, which starts on Page 3, titled scope and summary of opinions, is an outline of the information that's found in the report going forward; right?

A. Yes.

Q. Section 3 is titled introduction to cancer, and that's found on Page 6.

Do you see that?

A. Yes.

Q. Let's go through this a little bit. This -- we'll rephrase.

This introduction to cancer section is really just a general overview of certain concepts related to what cancer is and how it occurs in the body; right?

A. Yes.

Q. At the bottom of Page 7, you state, "Environmental factors that contribute to the cause of cancer have been described and can be specific to certain cancer types. Environmental factors include aspects of lifestyle, economic, and behavioral exposures. Poor diet, inactivity, and sedentary lifestyle, and obesity, and metabolic syndrome have each been associated with carcinogenesis.

Some specific foods are linked to specific cancers."

So going through what you just read, that again is an overview of the fact that there's things that we're exposed to in our day-to-day lives that can cause or contribute to cancer; correct?

MR. INSOGNA: Object to form.

A. As an overview, there are a lot of different etiologies of cancer, and I list some of the main categories there.

BY MR. SLATER:

Q. On Page 8, the second full paragraph says, "Broadly speaking, any factor that may alter one's DNA sequence could contribute to carcinogenesis and the ultimate development of cancer and could be referred to as a carcinogen."

Correct?

A. That's what that says, yes.

Q. Just -- rephrase.

Looking at the first paragraph on Page 8, you talk about hypertension as being associated with increased cancer risk and cancer mortality.

Correct?

A. Yes.

Q. And you state that this is "particularly

as it also tracks and closely associates with other cancer-related risk factors of smoking, alcohol use, obesity, diabetes, diet, and other factors"?

A. Yes.

Q. And then you say, "After adjusting for these known cancer risk factors, however, hypertension is also potentially an independent cancer risk factor in a number of tumor types, including renal, colorectal, breast, esophageal, liver, and uterine cancers."

Correct?

A. Correct.

Q. And when you say potentially, you're saying it's possible; right?

A. Right.

Q. Did you say yes?

A. Yes, I said right.

Q. Okay.

A. I said that -- I can expand on that, that the data that looked at those studies concluded that it's after adjusting for all the known and associated confounders, which are listed there, that there remained what appeared to be an association, but that's why it's still potentially associated, because despite

trying to adjust for confounders, there's always residual confounding that's difficult to measure and adjust for.

So either way, the point I was making here is that whether it's actually associated independently or because it's associated with all the other things that we know are associated with cancer, hypertension is associated with cancer.

Q. Again, when you say hypertension's associated with cancer, as we just read through, my understanding was that it's something that is seen but there's these other independent factors that you have to adjust for.

Do I understand that correctly?

A. And -- yes, and after adjusting for them in some reports that I reference here there was residual association with hypertension and cancer, suggesting that there's a potentially independent association with hypertension even aside of all the other things that we're talking about here.

Q. And the studies that you cited there -- you're saying there was a potential association shown.

Is that because the association didn't achieve statistical significance?

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A. No, I think that's -- that's scientific language to say that we have to be cautious with our interpretations of studies, and finding an association in a given analysis is not definitive from one look, and so a conservative way to say that there's still potential association that merits further investigation, for example.

Again, my point there was to suggest that whether it's independently associated or associated by proxy, it's associated with cancer -- hypertension.

Q. Just for the record, I'm not going through Section 4, the cancer prevention, screening, and incidence section, because I read that as going to the medical monitoring, so I assume we should skip that.

Then we have Section 5 on Page 12. Cancer -- actually, it should be -- yes. Looking -- new questions.

Looking at Page 12 at the top, cancer symptoms, diagnosis, and staging, Section 5.

Does that section relate specifically in any way to the question of whether or not the NDMA or NDEA can cause cancer in humans?

MR. INSOGNA: Object to form.

BY MR. SLATER:

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Q. Or is it just background information?

A. No, it's background information.

Q. Looking at Section 6, cancer treatment.

Is that also background information?

MR. INSOGNA: Object to form.

A. Not all of it. As you can see in Page 13, the last paragraph of Section 6 is discussing the notion that these -- the NDMA and NDEA identified in valsartan could potentially affect how one treats the cancer or how one's cancer responds to treatment, and so I pointed out that there's no such evidence that it has any impact on how one approaches cancer treatment in any way.

BY MR. SLATER:

Q. When people are undergoing treatment for lung cancer, is it suggested to them that they should stop smoking?

A. We suggest that to everybody, because smoking can make things worse even in the setting of when you already have cancer. So we would always say that, but in fact in many cases, like with my patients who we're treating with end-of-life cancers, terminal cancers, who actually at that point the treatment is with the intention to palliate them and to optimize

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quality of life as long as possible, I often say this is not the time to stop, you might as well enjoy life. So -- honestly. So that's -- in some cases, no, we don't.

Q. And looking at Section 7, posttreatment cancer surveillance, that again is medical monitoring, so I'm not going to get into that. Okay.

Looking now at Section 8, which starts on Page 13. There's a discussion of specific cancers, and it goes all the way through Page 29.

A. Yes.

Q. The specific discussion of these various cancers is background information and is not specifically significant to your opinions as to whether or not NDMA and NDEA can cause or contribute to cancer in humans; correct?

MR. INSOGNA: Object to form. Compound.

A. I think the information is impertinent that's in here, from a couple of standpoints. One is the -- it talks about the incidence of cancer. And -- as a whole, but also each one of these. And also the risk factors that one has to consider, and how common these cancers can be, based on how common these risk factors are.

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So I think that's a pertinent background understanding when you're talking about now another putative variable that might be associated with cancer risk is to put that in a context of what's already happening and why and to take that into account.

But I don't -- I think it's more than just background. I think it's part of an important consideration. And these things come up again I think later in the later sections, when we're talking about some of the FDA referenced risks of these agents in valsartan, and putting that in context of what the base rate and risk is of getting cancer in society. So I think that that's important to consider.

BY MR. SLATER:

Q. How does the incidence of these cancers specifically relate to the opinions that you're offering as to whether or not NDMA and NDEA can increase one's cancer -- risk of cancer?

MR. INSOGNA: Object to form. Misstates testimony.

A. I think they're important to consider when looking at the risk or lack thereof of something else on top of what we already understand.

But in terms of what the risk is, if any,

of the putative exposures to valsartan-containing drugs that had impurities, that's not actually pertinent to the analysis that I did, in terms of the epidemiological analysis, dietary studies, the occupational exposures, and the animal data, per se, in terms of me making an opinion whether or not there is added risk.

But I -- what I was alluding to was if we went to the next section, where the FDA is indicating sort of like the one -- above the accepted daily intake and what the risk is for a patient taking it at that daily intake for 70 years, taking that into account, you must understand what the basal incidence of cancers are to put that into context.

BY MR. SLATER:

Q. Whatever the baseline incidence of cancer is, either NDMA and NDEA people are exposed to day-to-day either is contributing to that incidence level or not; right?

MR. INSOGNA: Object to form. Argumentative.

A. Can you rephrase that?

BY MR. SLATER:

Q. Yeah. You spoke about the cancer

incidence being relevant, and then talked about adding something to that risk level. I think that's what you were saying. What I'm asking is this.

If you have an incidence rate of a particular cancer, as you reflected it here, that incidence rate isn't making any judgments as to what's causing that incidence rate; right.

MR. INSOGNA: Form.

A. I'm not understanding your question.

BY MR. SLATER:

Q. You gave me incidence rate -- rephrase.

The report state some cancer incidence rates; right?

A. Yes.

Q. In and of itself, the incidence rate of cancer doesn't tell it how it's being caused or what's contributing to the cause of that cancer; right?

A. Not in and of itself, but we know -- for example -- let me clarify.

We know that these agents became online in 2012, and we know what the incidence rates of cancer have been over the last decade, so we can look at incidence rates before and after, and we can analyze to see are there any increases in incidence, which we're

going to get to when we talk about the epi data, in terms of the additional contribution of these drugs, does it cause any extra risk.

So you need to sort of know what the basal risk is to begin with, from all the known associations and mostly unknown reasons why patients get cancer.

Q. There's no such study that was set up to measure in a general sense the increased risks of cancer in general as of 2012; right? There was the studying you're talking are Gomm and Pottegard, where they compared different sets of people in the cohort; right?

A. That's true about Gomm and Pottegard. But we also know, as you've pointed in my report, that the incidence of cancer has been increasing steadily over the last decade, and you can see that the projection is that it will become even more common in terms of cancer mortality in the country.

So understanding and knowing that is I think an important thing to take into account as a basal understanding of what we're talking about in terms of cancer risk.

Q. Are you specifically relying on cancer inc -- cancer -- rephrase.

Are you relying on any specific cancer incidence rate as a basis for your opinion as to whether or not NDMA and NDEA can cause any increased risk of cancer to humans?

A. No.

MR. INSOGNA: Object to form.

A. No, I'm relying on that for that part of the opinion.

BY MR. SLATER:

Q. In terms of the lists of risk factors that you provide for these various cancers, did you list nitrosamines as a risk factor for any of them?

A. I -- in this section in the background, no, but we talked about it in the -- nitrosamines in the diet section, where that would be pertinent.

Q. Do you agree NDMA and NDEA intake is a risk factor for cancer as a general proposition?

A. No.

Q. Not for any cancer?

A. I think -- I think it's been found to be associated in some studies that I think we're going to get to.

Q. Bear with me for one second. I'll be right back.

Let me just make sure that I'm asking this question clearly.

Do you agree or disagree that -- let me rephrase.

Do you agree or disagree that nitrosamines are a risk factor for any cancer, yes or no?

MR. INSOGNA: Object to form.

A. I disagree.

MR. SLATER: Chris, do you have handy the article authored by Dr. Catenacci and another author titled "Toward Personalized Treatment of Advanced Biliary Tract Cancers"? If you do, please put that up on the screen as the next exhibit.

MR. GEDDIS: I'll --

MR. SLATER: What?

MR. GEDDIS: I'll enter it as an exhibit.

MR. SLATER: Yeah. Yeah. Sorry. I didn't hear what you said. Yeah.

[Exhibit 12 marked for identification.]

BY MR. SLATER:

Q. Doctor, do you see on the screen -- and actually, I don't know what number we're up to. Let's just for the record say what exhibit number this is, if anyone knows.

MR. GEDDIS: 12.

THE REPORTER: Yeah, Exhibit 12.

MR. SLATER: Great.

BY MR. SLATER:

Q. Doctor, on the screen is Exhibit 12. It's an article titled "Toward Personalized Treatment of Advanced Biliary Tract Cancers," published in a journal called Discovery Medicine in July 2012.

Do you see that?

Q. You're one of the coauthors of that article; correct?

A. Yes, along with my fellow, Dr. Geynisman.

MR. SLATER: Chris, could you scroll down a little bit and then blow up a little bit the introduction at the bottom of that page? Just that first paragraph right there, yeah. That's it. Perfect.

BY MR. SLATER:

Q. This starts out in the introduction stating, "Biliary tract cancers are comprised of four distinct adenocarcinomas: Gallbladder carcinoma; intrahepatic cholangiocarcinoma; hilar cholangiocarcinoma, also known as a Klatskin tumor and further subclassified by the Bismuth criteria; and D,

extrahepatic cholangiocarcinoma."

You see that?

A. Yes.

Q. What is -- well, rephrase.

What is the biliary tract?

A. Biliary tract is a set of ducts within the liver that excrete bile into the small bowel, and they also in the bile have enzymes and other factors that help with digestion, and it's also a common route of excretion of degradation products and chemicals.

Q. Are nitrosamines, including NDMA and NDEA, metabolized in the liver?

A. Yes.

Q. What does that mean for them to be metabolized in the liver?

A. When you have NDMA or others, they -- if we're talking about an oral uptake or endogenous in the gut, they get absorbed and they get transported to the liver as first path to the portal venous system, which all things taken orally do.

And based on enzymes that are in the liver cells, they metabolize things, called first-pass metabolism, that in that case would actually -- part of the metabolism pathway would convert the NDMA to an

active metabolite, and then would be excreted through the biliary system after a number of chemical processes that make it conducive to being excreted through the bile, through the biliary tract system that we were talking about.

Q. Let's go, if we could, to the second page of this article, which is Page 42, the right-hand column. And there's a heading that says "epidemiology and etiology of biliary tract cancers."

Do you see that?

A. Yes.

Q. I'd like to go down towards the bottom of that column and read this, and then we'll read over to the next page.

Towards the bottom of that page, six lines up from the bottom of that paragraph in the right column, it says, "Whereas the majority of patients have no identifiable etiology, known risk factors include chronic inflammatory diseases, including" -- and then there's a list of those diseases.

Do you see that?

A. Yes.

Q. And if you continue on the next page --

MR. SLATER: Can you scroll to the top of

the next page, please, Chris? Perfect.
BY MR. SLATER:
Q. After that list, it says, "Chemicals such as dioxin nitrosamines and asbestos," and then lists some medications and then "other general exposures and behaviors, including smoking, obesity, and diabetes. Many of these presumably lead to a state of chronic inflammation, cancer initiation, and progression."
That's what you wrote in this 2012 article; correct?
A. That's what's written there, similar to as I pointed out in the gastric paper that I referenced here -- that it was mentioned in that particular paper. It's the same concept in that it's an association that's been reported. I wasn't -- I was just -- we were trying to show all of the literature that's reported on various associations that have been described.
Q. My question is this. It's more narrow than what you stated. Here's my question.
In this article you published in 2012, that is what you stated; correct?
A. We stated that it was one of many associations with this cancer, but without going into

detail, because that wasn't the focus of this paper.
Q. Well, I don't see the word "association" in that paragraph because it doesn't appear in that paragraph; correct?
MR. INSOGNA: Object to form.
A. That's what's implied.
BY MR. SLATER:
Q. Is the answer to my -- my question is this. New question.
The word "association" does not appear there; instead you use the word "known risk factors."
Correct?
A. That's what is used in that -- the terminology that is used there, yes.
Q. And the specific terminology relative to what we're talking about here in this deposition is that you in a published article in 2012 said that the known risk factors for these biliary tract cancers includes chemicals such as nitrosamines; correct?
A. It does say that. I'm telling you that implies that these are what have been associated in the literature. I'll point out it doesn't say NDMA or NDEA.
Q. This refers to nitrosamines as known risk

factors; correct?
MR. INSOGNA: Object to form.
A. As explained before, but it does say nitrosamines as a group.
BY MR. SLATER:
Q. Within the group of -- rephrase.
This states that nitrosamines are known risk factors for biliary tract cancers, and that includes NDMA and NDEA? They are nitrosamines; correct?
MR. INSOGNA: Object to form. Compound.
A. Those are one of hundreds, I believe, of different nitrosamines. So this is not specific to any one. It's an overall review paper noting previously reported associations with these cancer.
BY MR. SLATER:
Q. As you sit here now, you agree with me that nitrosamines, including NDMA and NDEA, are known risk factors for biliary tract cancer; correct?
MR. INSOGNA: Object to form.
A. As we'll talk about when we get to the studies looking at nitrosamines in dietary and other studies, there are well-recognized papers, many of which we talk about here, that suggest association of

nitrosamines with various cancers.
BY MR. SLATER:
Q. In terms --
A. And there are other --
Q. In terms of my specific question, you agree with me as you sit here right now that nitrosamines, including NDMA and NDEA, are known risk factors for biliary tract cancers; correct?
MR. INSOGNA: Object to form. Asked and answered.
A. I'm trying to tell you that what that means is that there are known papers that reported associations with nitrosamines for various cancers, and I pointed one out earlier, including this one, and I think we'll talk about it later when we get to the dietary papers.
BY MR. SLATER:
Q. I'm not asking about where, when, or why. I'm just asking this question.
As you sit here now, you agree with me that nitrosamines, including NDMA and NDEA, are known risk factors for biliary tract cancers; correct?
MR. INSOGNA: Object to form. Asked and answered.

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A. There are known reports that have looked at that association and various cancers, including biliary tract cancers.
BY MR. SLATER:
Q. Is the answer to my question yes, that they are known risk factors?
MR. INSOGNA: Object to form. Asked and answered.
A. There are known -- there are known papers that have looked at them as risk factors and reported associations in both positive and negative studies.
BY MR. SLATER:
Q. Again, I'm not asking about other papers. I'm not asking about the why or wherefore. It's a very narrow, very direct question.
Do you agree with me as you sit here now that nitrosamines, including NDMA and NDEA, are known risk factors for biliary tract cancer?
MR. INSOGNA: Object to form. That's the fourth time you've asked the question. He's answered it.
A. The way you're asking that question, the answer is no.
BY MR. SLATER:

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Q. When you stated in your paper in 2012 that you published that nitrosamines are known risk factors for biliary tract cancers, was that a true statement?
MR. INSOGNA: Form.
A. I'm telling you what was meant by that statement and that there are known associations of nitrosamines with this cancer that was the topic of this paper that have been reported.
Whether I agreed with that comment or not, I was -- as we talked about earlier, I was reporting what has been reported in other papers as a review article, not even in detail.
BY MR. SLATER:
Q. Was that a true statement when you made it in your paper in 2012?
MR. INSOGNA: Object to form. Asked and answered.
A. As I stated, yes.
BY MR. SLATER:
Q. The answer is yes; correct?
MR. INSOGNA: Object to form. Asked and answered.
A. As I stated, that is correct.
BY MR. SLATER:

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Q. Well, I just wanted it -- honestly would appreciate just -- it hasn't been asked and answered, because I don't know what "as I stated" means, I don't know if that's supposed to bring in all the other things I didn't ask about, so I would really appreciate it, Doctor, if you could just answer this question with a direct yes or no.
When you stated in 2012 in a published article that nitrosamines are known risk factors for biliary tract cancer, was that a true statement? Yes or no?
MR. INSOGNA: Object to form. Asked and answered. He does not have to answer the question the way you want him to. The --
A. I can't answer that yes, no, without the qualification and the explanation I've given a few times now.
BY MR. SLATER:
Q. Doctor, the explanation can be requested either by me in a subsequent question or by defense counsel when they get to question you. I didn't ask you why it's true, and I didn't ask you why you said it, but you keep telling me that, so that's -- but that's not what I'm asking. So I'm going to try this

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again with you.
When you stated in a published paper in 2012 that nitrosamines are known risk factors for biliary tract cancers, was that a true statement? Yes or no?
MR. INSOGNA: Object to form. Asked and answered.
A. I answered that as best as I can up until this point.
BY MR. SLATER:
Q. Was it a true statement? Yes or no?
MR. INSOGNA: Object to form. Asked and answered.
A. It is true that it was an association that was recognized in a number of papers that nitrosamines and all the other things listed there are associated with this cancer.
BY MR. SLATER:
Q. Yes or no?
MR. INSOGNA: Same objection.
A. What's the question?
BY MR. SLATER:
Q. When you stated in a published paper in 2012 that nitrosamines are known risk factors for

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biliary tract cancers, was that a true statement?
MR. INSOGNA: Same objection. Asked and answered.
A. I can't answer that any other way than I already have. I can keep giving you the same answer.
BY MR. SLATER:
Q. Well, Doctor, you're an expert witness here, so this isn't your first time in a deposition, and you understand that you're supposed to answer the questions as directly as you can.
If the lawyer who hired you who's sitting to your side wants to ask you why is that a true statement and you want to talk about associations and things, you certainly can do that in a subsequent part of the deposition, but I'm not asking you the why, and I'm not asking what it meant. I'm asking as it's phrased in this published paper.
MR. INSOGNA: Counsel --
BY MR. SLATER:
Q. So I'll try it one more time. Perhaps with that clarification, we can get past this speed bump.
When you stated in a published paper in 2012 that nitrosamines are known risk factors for

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biliary tract cancers, was that a true statement? Yes or no?
MR. INSOGNA: Same objection. Asked and answered. He has just stated he has no other way to answer this question. You can continue to bully him, he can continue to give you the answer. You can answer it again.
A. We all see the statement. I was trying to make sure that the underlying intention and meaning of the statement was relayed.
BY MR. SLATER:
Q. If you want to relay the underlying intention and the meaning of the statement, I'm sure that you can tell during a break the lawyer who's sitting to your side, and then he'll ask you the question later, or maybe I'll follow up with it, but I'm just trying to go step-by-step. So starting with the simple, I'll try it one more time.
When you stated in a published paper in 2012 that nitrosamines are known risk factors for biliary tract cancers, was that a true statement? Yes or no?
MR. INSOGNA: Same objection. Asked and answered.

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A. The statement is there, and I defined what it means.
BY MR. SLATER:
Q. The statement that was made in this paper -- is that a true statement or not?
MR. INSOGNA: Same objection. Asked and answered.
A. A descriptive statement of available studies as a review paper.
BY MR. SLATER:
Q. Doctor, is there a reason why you don't want to just say that what you wrote in a published paper was true? You keep saying you want to explain why it's true and what you meant by it, but I'm not asking you that question. I'm just asking if what you published was a true statement.
I would really appreciate it if I could get -- this -- we were asked before how long this is going to take. We've now hit, "It's not going that quick." So I'm going to try it one more time.
When you stated in a published paper -- I don't know why you're looking at your counsel, if you are looking at counsel. Right?
But you don't need -- let me just say

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something. I've been watching this the entire deposition, in good faith, assuming that Dr. Catenacci is just waiting for objections. But I don't think that he needs to look at you every single time he answers a question, and I don't appreciate it, because I don't think that's appropriate.
MR. INSOGNA: Adam, there's --
BY MR. SLATER:
Q. So I'm going to try this again.
MR. INSOGNA: Adam, there is an attorney for your side in the room who can tell you that --
MR. SLATER: I don't care. I'm going to try to continue this deposition. I'm commenting on the record that Dr. Catenacci -- and we have a video, it will speak for itself -- is looking at you almost every single time I ask a question. Okay? So I'd prefer to just --
MR. INSOGNA: I have to correct that colloquy, because it's inaccurate. There are two screens, one in front of you and one to the doctor's right where the document is being shown. You have an attorney for your side present in the room who can tell you if he's looking at me or if I'm looking at him, and I am not. I am looking directly at the screen. Okay?

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You've asked this question probably eight times now. He has given you his answer and told you that's the only way he knows how to answer the question.

MR. SLATER: And counsel, I don't want to argue with you, okay, because we can do this if we need to at another time in another venue.

BY MR. SLATER:

Q. When you stated in a published article in 2012 that nitrosamines are known risk factors for biliary tract cancers, was that a true statement? Yes or no?

MR. INSOGNA: Same objection. Asked and answered.

A. That is the statement that's there, and I've qualified what I meant by it.

BY MR. SLATER:

Q. Is it a true statement? Yes or no?

A. As I answered, it's true.

Q. As you sit here right now, it's true that NDMA and NDEA are known risk factors for biliary tract cancers; correct?

MR. INSOGNA: Same objection. Asked and answered. Now misstating the document.

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MR. SLATER: It's actually a different question. I'll ask it differently.

BY MR. SLATER:

Q. As you sit here right now, are nitrosamines known risk factors for biliary tract cancers?

A. No.

Q. They're not known risk factors anymore? That changed since 2012?

A. There are associations that have noted nitrosamines through various ways, whether it's occupational, whether it's by diet, that have shown associations with various cancers. There are similar papers that have shown no associations.

And so if you're asking me if there's a known risk factor for this, first of all, it's quite vague, because what -- are we talking about how -- what are the exposures, at what levels, et cetera?

So as you asked it, the answer is no.

Q. Well, I'm using the language you used in your published peer-reviewed article, so I'm not using any language that's foreign to you, because this is your own words; right?

A. I'm trying to explain those to you so that you under --

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Q. Well, I haven't asked you to explain them, though, and you keep trying to explain them, and I don't really understand why. I'm asking you one question, and you're answering one I didn't ask you, and they're very different.

So I would appreciate -- if I don't ask for an explanation, there's no need to give me an explanation.

A. Is there a question?

MR. INSOGNA: There's no question.

BY MR. SLATER:

Q. There is peer-reviewed literature establishing an association between NDMA and NDEA and human cancers; correct?

A. Establishing associations?

Q. Yes.

A. Yes, I think I referenced some of them and discussed them, that there are papers that have reported associations in various cancers and various assessments.

Q. You refer in this section of the report to medical societies and whether they list NDMA as a risk factor for certain cancers; right?

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A. Yes.

Q. You don't list those medical societies -- rephrase.

You don't list the actual medical society statements in your list of materials considered; right?

A. Right. As I mentioned earlier, when it was something that was common knowledge that I didn't need to reference, just based on these are statements that we do every day in terms of clinical care of our patients.

Q. The actual statements that you're referring to are not listed in your list of materials considered nor were they provided to us with your materials considered; right?

MR. INSOGNA: Object to form.

A. Other than the answer I provided, no, they're not there.

BY MR. SLATER:

Q. And for example, you didn't provide the dates of those society statements or the methodology that was followed by them coming up with these purported statements; right? That's not discussed in the report; right?

MR. INSOGNA: Object to form.

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A. I didn't put that explicitly in the report, no.
BY MR. SLATER:
Q. If I understood your -- rephrase.
If I understand your thinking, you use the word "risk factor" and "association" essentially interchangeably. Do I understand that?
MR. INSOGNA: Object to form. Misstates the testimony.
MR. SLATER: Well, I'm not misstating it; I'm asking it. So I don't know why you're objecting, counsel. Are you telling him to disagree with me, or -- I don't understand the objection. What's the objection?
MR. INSOGNA: My objection is you've characterized his testimony -- I think you've mischaracterized. He can answer you if he disagrees with me. If he disagrees with you -- I told him he could answer.
MR. SLATER: Okay. Well, I didn't characterize it. I actually asked if my characterization was accurate. It's a different question. I have an issue with your objection, because I feel like it can be a suggestion, perhaps, as to how

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to answer the question, so I'm just flagging that for the record.
MR. INSOGNA: My understanding is that we are allowed to give explanations for our objections, but noted.
BY MR. SLATER:
Q. Do you equate a risk factor with an association?
A. Not always, but in this instance where we were talking about various things that have been associated with cancer and being well-recognized as potential risk factors for cancer, we listed all of the references that were there that have been in the literature.
Q. You're talking about your article in 2012?
A. And also, similar to the other one, where we were doing a review on gastroesophageal cancer and we were -- mentioned a similar phrase. I think in that actual paper it says associated with, as opposed to a risk factor.
Q. With regard to all the cancers that were listed, there is literature suggesting association for each of them, thus you would consider NDMA and NDEA to be risk factors for each of those cancers; correct?

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MR. INSOGNA: Object to form.
A. Bit of a vague question. Can you be a little bit more detailed which cancer we're talking about?
BY MR. SLATER:
Q. You went through a whole series of cancers in section --
A. Yes.
Q. And my question is this. Because there is literature suggesting an association between NDMA and each of those different cancers, would you agree that there's at least an association thus that those substances are risk factors for those cancers?
A. I would say potential risk factors, which in the end I think is another way to characterize that paragraph, would have been potential risk factors.
Q. We talked earlier about precision in writing a report or a peer-reviewed article; right?
A. Yes, we did.
Q. You didn't use the word "potential" in either your article in 2012 or the report; right?
A. The report? I didn't talk about nitrosamines in this particular paragraph.
Q. You actually did not recognize at all in

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your report the fact that nitrosamines are potential risk factors as you now state for these cancers. That was not stated; right?
MR. INSOGNA: Object to form.
A. That's not true. I talked about them as a whole section later on, and the data for and against it.
BY MR. SLATER:
Q. Well, I'm talking about in this section, the introduction to cancers summary, where you suggested through your reference to the lack of medical society listings of NDMA as a risk factor, you were suggesting it's not a risk factor; right?
A. I'm suggesting that these are all potential -- that are association studies that have shown some degree of association. That makes them potential risk factors.
Q. Well, you didn't say, "Even though the medical societies don't list NDMA or NDEA as risk factors, in my opinion they are potential risk factors for these cancers"?
That's not stated; correct?
MR. INSOGNA: Object to form.
A. My opinion is not that NDMA is a risk

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factor as a blanket statement without qualifying discussion about it.
BY MR. SLATER:
Q. Well, I said potential risk factor, which was your phrase.
It doesn't say that; right?
A. Well, I didn't say -- sorry.
MR. INSOGNA: Object to form.
A. I didn't that about NDMA. I thought we were talking about nitrosamines.
BY MR. SLATER:
Q. I'm talking about your report and the language you used in your report. I thought that's what we were talking about.
A. I thought we were talking about --
MR. INSOGNA: There's no question pending.
BY MR. SLATER:
Q. Let's go now to Section 9 of your report on Page 29, please. You have a section titled valsartan and valsartan-containing drugs. That's Section 9. And then 9a is background, generic medications incorporating valsartan.
Do you see that?
A. Yes.

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Q. That's just background information about what the medications are supposed to do; right?
A. Yes.
Q. The presence of NDMA or NDEA in these medications would provide no benefit whatsoever; right?
MR. INSOGNA: Object to form.
A. They should not provide known benefit that I'm aware of.
BY MR. SLATER:
Q. Looking now at Page 29, 9b, where you say that VCDs and ARBs are not associated with an increased cancer risk.
You start out talking about an FDA meta-analysis that was reported on June 2, 2011; right?
A. Yes.
Q. You didn't think that we were claiming in this case that valsartan in and of itself without contamination with NDMA or NDEA causes cancer, did you?
A. That was not my opinion or the intention of including this section. The intention of including this section is that first of all there were studies analyzing it, and I thought it was pertinent to understand that the drug by itself prior to any of this happening -- this was done on June 2nd, 2011 -- did not

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have any association with cancer.
Q. Let's talk about that for a moment.
As of the reporting of this data in this meta-analysis of 2011, you would not expect that there would have been any NDMA or NDEA in valsartan; right? There's no reason to believe there would have been; correct?
A. And besides this is -- when the study was done, this was looking at a meta-analysis of studies done even before that. But yes, so the answer is yes, we wouldn't have expected to be any impurities there.
Q. So we know that on this meta-analysis conducted by the FDA as of 2011, when we know there was not NDMA or NDEA in valsartan, the study showed there is no increased risk of cancer at all; right?
A. That was important, I think, to understand as a background to the question at hand.
Q. Now let's look at Section 10 on Page 30, relevant background, VCDs with NDMA or other impurities.
Do you see that?
A. Yes.
Q. You start out talking about in June 2018, ZHP reported that it had detected the presence of a

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previous undetected impurity, NDMA, in the active pharmaceutical ingredient for valsartan; right?
A. Yes.
Q. Have you been shown any documents indicating that ZHP actually knew that there was NDMA in its valsartan before June 2018?
MR. INSOGNA: Object to form.
A. Not that I'm aware of.
BY MR. SLATER:
Q. You would agree with me that -- well, I'll withdraw that.
Why did you point out that it was previously undetected? Just because -- well, rephrase.
Why did you point out that this was previously undetected?
A. I believe I got that from the FDA website where I got this information. In other words, that it was -- there was a time point at which it was not known to be there.
Q. Did that -- was that of any significance to you in forming your opinions?
A. Not for the questions at hand for me, no. Other than, I mean, when we're talking about the duration of exposure, we'd want to know when it's

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thought that this was first -- when they first began having these impurities, which I think was determined, and so we know it was in 2012, I believe.

So that would be an important thing to understand, because when we look at the epi data, the studies are looking at the time point at which the drugs were available.

Q. And then evaluating the epi data, it's important to have a good understanding of which of the subjects in the study took valsartan contaminated with NDMA and which were not taking contaminated NDMA -- contaminated valsartan; correct?

A. That would be an important thing to do in that study, which is what was attempted to be done, yes. Both of the studies -- Pottegard and Gomm.

Q. In fact, the structure of the study relies heavily on assumptions as to which people were exposed to contaminated valsartan and which were not; right?

MR. INSOGNA: Object to form.

A. Attempts were made to identify which lots were involved and which ones weren't, and they defined them as definitely not, probably, and possibly. And they looked at it through different sensitivity analyses, excluding the possibly, just the probably, to

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make sure that the conclusions were consistent.

BY MR. SLATER:

Q. Well, to the extent --

A. That was what was available. That's the best evidence that was available to them.

Q. If that -- rephrase.

If those assumptions were wrong, that could impact the data and the significance of the data; right?

MR. INSOGNA: Object to form.

A. They -- the answer to your question is that if assumptions are wrong in a study, they can affect and influence the outcome of the data, as in any study. And those assumptions I think, in my opinion, after reviewing the papers and what they did to identify those, is really the highest quality evidence that we have to look at this question to date.

BY MR. SLATER:

Q. We'll come back to that; I promise.

Looking at your report, Page 30 to 31, you quoted some FDA statements, including the statement that, "Patients taking the recalled valsartan-containing medicines should continue taking their medicine until they have a replacement product."

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You quoted that there; right?

A. Yes.

Q. The understanding was you're taking valsartan due to hypertension and to prevent significant cardiovascular injury versus the risk of using the drug for a short period of time further and entertaining a potential risk of cancer?

That's basically what was being weighed; right?

A. Right. It was weighing risks and benefits of things, and I think that's why I pointed it out, that it was felt that the risk of stopping the drug was worse than continuing the drug until replacements could be found.

And later down I think I pointed out that the risk -- the actual risk of not taking valsartan for hypertension is actually really minimal, so sort of shows you how minuscule the risk was of continued impurity in the VCDs.

I think that's on page -- I'd have to look and see exactly which page to point you to that, but it's in there. So --

Q. The FDA in statements consistently told patients to make sure they spoke to their doctor and

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secured a replacement medication before ceasing their valsartan; right?

MR. INSOGNA: Object to form.

A. Can you repeat that again? I missed the beginning of the question.

BY MR. SLATER:

Q. What we just read states that patients should speak to their doctor, continue taking the valsartan until they have a replacement product.

That's what the FDA told people; right?

A. Yes, that's what we just talked about. In other words, the risk of stopping it was larger than taking it if it had an impurity in it. That's how I see that.

Q. Right. The risk of stopping it encompassed the risk of having, for example, a heart attack the next day; right?

That's one of the risks; right?

A. That's one of the risks, and that's why I was pointing you to Page 33 at the top. The actual risk is actually small in stopping the drug, but it's better -- they're standard treatments to take for these conditions because they improve outcomes, but the actual improvement is actually marginal.

And despite that, they still were told to stay on it instead of stop them, which tells me that the calculated risk of continuing the drug was low compared to stopping it.

Q. Where are you saying that the FDA said taking the medication act -- rephrase.

Where are you pointing to where it says stopping the medication actually doesn't create any risk or creates very little risk?

A. Reask -- say that again. Clarify the question.

Q. I thought what you just told me is that the FDA later came out and said that the risk of stopping your valsartan and having any sort of an adverse event as a result of stopping your hypertension medication is very, very small.

Did I misunderstand what you said?

A. You misunderstand what I said. If you go to Page 33, this is now my interpretation of what statement that FDA said was, is that when you look at the actual risk reduction of adverse events that hyper -- that valsartan and other blood pressure medications mitigate, they do improve outcomes, but they're not dramatic improvements.

In other words, if you were to stop it, it wouldn't be -- there was no survival differ -- all causes of death did not show any differences between these groups. So in other words, stopping it wouldn't have had that much of a detriment.

But despite this knowledge and knowing about these drugs, the FDA adjudicated that it was still worth staying on the drug because the risk of taking the valsartan-containing impurities was even lower than that. That's my point.

Q. So you think the FDA told people to keep taking their valsartan so they wouldn't have, for example, a heart attack or a stroke or some adverse cardiovascular event, and that the FDA thought that was a minuscule risk and told people to keep taking the drug anyway?

MR. INSOGNA: Object to form. You may --

BY MR. SLATER:

Q. Is that your testimony, Doctor? Like does anybody agree with you in the world about that that you know of?

A. Let me answer it in a different way so you understand what I'm saying.

If it was calculated that the risk of

taking these drugs was higher than the risk of continuing -- and stopping the valsartan drugs, then they would have said stop the drug, because the risk of stopping was not as high as continually taking them.

Does that make sense to you?

Q. Well --

A. So they were saying the risk that we calculated is very low, as I quoted several times, and that it's better to stay on the drug, because that's more of a risk to stop it.

And I'm telling you when you calculate that risk of stopping it, it would be very small, which tells you that the risk of continuing the valsartan-containing drugs with impurity is even smaller than that. That's all I'm saying.

Q. All right, but in the real world, what the FDA was telling people is, "We don't want you to get off the drug for days or weeks while you look for a new replacement drug"?

That's what they told people; right?

A. Because it was felt that it was not that much of a risk to stay on it. To stay on the drugs, it wasn't that much of a risk. If it was deemed to be a higher risk, they would have said stop the drugs, it's

worth stopping them, and accepting the risk of not getting the benefit from the blood pressure medicine.

Q. What they said is the risk of stopping the blood pressure drug, which could kill you in a couple of days potentially, was considered to be a worse choice than continuing to take the pills for a few more days or even a few weeks, which could potentially cause cancer down the line?

That was the trade-off; right?

MR. INSOGNA: Object to form.

BY MR. SLATER:

Q. That's the trade-off the FDA was providing; right?

A. The FDA was calculating what the risks were of staying on the drugs or not staying on the drugs, and the consequences of each approach. And they obviously stated that they thought the risks of staying on it were minimal, and to stay on the drug, because the risks of stopping it was higher from getting a cardiac or other complication.

And what I'm telling you is those actual risks are low when you look at the data in that paragraph on top of Page 33. That's why I included that there.

In a different scenario, different hypothetical scenario, if the risk of a drug became higher of continually taking it than actually just stopping it, then they would have said that instead. That's my point.

Q. This was the risk of getting off the drug for a couple of days, because they only wanted people to stay on the drug for a very short time until they could get a replacement?

That's what the FDA said; right?

MR. INSOGNA: Object to form.

BY MR. SLATER:

Q. Is that what the FDA said, Doctor?

A. It stated here -- and I think we agree on that, and what I'm trying to tell you is the interpretation is that the risk was considered very minimal, which I think is verbatim from what they've said, is that the actual risk is very low.

Q. Did the FDA -- did the FDA say, "Well, go ahead and stay on the valsartan with the contamination with NDMA and NDEA for the rest of your life. Go ahead. No problem"?

Did the FDA ever say that?

A. No, they did not say that.

Q. What the FDA did was address a potential drug shortage because of how widespread the contamination was, address the risk of getting off your hypertension medication for a few days?

That's what the FDA was looking at; right?

MR. INSOGNA: Object to form.

A. I think it was more than a few days. It was a few months that they were anticipating them to be on the drugs. And I think, as I said many times, they calculated what they thought the risks would be of staying on these drugs with impurities versus not, and the calculation was stay on them.

And what I'm telling you is that the consequence of stopping the drugs was actually considered quite small anyway, so that tells you that the risk of staying on them was quite minuscule.

BY MR. SLATER:

Q. Would you agree with me that it would be completely -- well, rephrase.

If a physician prescribing a blood pressure medication to a patient had a choice between valsartan-contaminated as these pills were and an alternative medication that wasn't contaminated with NDMA or NDEA, 10 out of 10 times the doctor would

recommend the uncontaminated pills that don't have NDMA or NDEA; correct?

MR. INSOGNA: Object to form.

A. That's a different question, and I would agree with that. If I had a choice, I would choose the one that doesn't have it. You were asking and we were talking about weighing the risks of taking it versus stopping the drug, and that's a different question. And the risk of stopping it was deemed higher than the risk of continuing it.

And what I'm telling you is that the risk of stopping it was a minuscule risk to begin with from the data that I quoted here, and that implicitly that means the risk was lower than -- in terms of just continuing it. It was a minuscule risk, and I think the FDA even stated it was a low risk for patients.

MR. SLATER: Just for the record -- and I want to just tell the counsel this just so I preserve my rights. I'm not moving to strike any of the questions during this deposition, because I was instructed not to, and that my rights are still preserved, so I don't want my lack of motions to strike to be interpreted by anybody as me not -- or be interpreted as me thinking that all these answers are

responsive.

I just want to place it on the record in case I have to -- in case I need that bookmarked for later.

BY MR. SLATER:

Q. There is no physician you can -- well, rephrase.

It would never be reasonable for a physician to recommend to a patient the contaminated valsartan pills that are at issue in this case versus comparable medication that's not contaminated with NDMA and NDEA?

You agree with that; right?

MR. INSOGNA: Object to form.

A. What is the question? Whether or not I would say to take the pills with or without? Is that what you're asking me?

BY MR. SLATER:

Q. There is no physician in your opinion who could reasonably recommend to a patient to take the valsartan with the contamination versus a comparable drug with comparable efficacy without the contamination; correct?

A. I think you asked that already, and I

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agreed, yes, that's true. That was different than the other questions you were asking me.
Q. And that's because there's, as you call -- rephrase.
And that's because why would anybody entertain this risk if you don't need to; right?
MR. INSOGNA: Object to form.
A. If you had a choice to not take it, then I agree with you, there would be no reason to do that.
BY MR. SLATER:
Q. There's no reason -- there's no reason to entertain that risk, right, if you don't have to?
MR. INSOGNA: Object to form.
A. There's no reason to take the drugs with impurity of NDMA or others because we already acknowledge there's no known benefit to it, so there would be no reason to do that.
BY MR. SLATER:
Q. Looking at page -- sorry, one second.
Looking at Page 30, the first paragraph under Section 10. You indicate, "According to tests of a random selection of API batches performed by ZHP, the levels of NDMA ranged from 3.4 parts per million to 120 parts per million, with an average of 66.5 parts per

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million."
And you reference 214 as the source of that information; correct?
A. Yes.
Q. And that's a document that was provided to you by counsel listing some NDMA levels; correct?
A. Yes.
Q. Did counsel ever inform you that there were other documents produced in this litigation that showed ZHP's valsartan was contaminated in some lots with higher levels than what you quoted in your report?
MR. INSOGNA: Object to form. I'm going to instruct you not to answer anything about what you discussed with counsel.
BY MR. SLATER:
Q. I -- well, let me ask it differently.
Were you provided any documents by counsel indicating higher levels of contamination with NDMA in ZHP's valsartan?
Were you aware of such documents?
A. I don't know. I looked at that document and also I looked at obviously the ones online that showed the values that were found in various lots and the ranges for both NDMA and NDEA.

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Q. In terms of internal corporate documents showing their testing, and in terms of the documents that we went through in discovery, you're only aware of those that were provided to you by counsel?
We already went through that; right?
A. Yes.
Q. And if you go to Page 34 and 35. You have a table -- it actually is 33 to 35.
You have a table of various test results, and that you got from the FDA; right? The FDA's information?
A. Yes.
Q. Did you get that independently, or was that provided to you?
A. I found that online independently.
Q. Did you ever ask counsel if these values were consistent with what we learned in discovery when we took depositions of corporate witnesses?
MR. INSOGNA: Object to form. Same instruction not to answer anything concerning what you discussed with attorneys.
BY MR. SLATER:
Q. Did you wonder if those levels were accurate or whether or not higher levels were

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potentially disclosed in discovery when we took depositions of witnesses?
MR. INSOGNA: Object to form.
A. I took the values that the FDA had as the public values and the ones provided here in that one reference in 214. I didn't think otherwise.
BY MR. SLATER:
Q. If there -- rephrase.
If the lawyers who hired you had data and documents from the manufacturers that reflected higher levels of NDMA and NDEA, you would have wanted to be provided those; correct?
MR. INSOGNA: Object to form.
A. Yes, I would like -- I think as we discussed earlier, I'd like to be able to look at all of the data to weigh in to see what is and isn't relevant and what is important.
BY MR. SLATER:
Q. Go -- rephrase.
Looking a little bit below where we just were talking at the end of the chart at Page 35. You discuss an April 4, 2019, FDA statement.
Do you see that?
A. Yes.

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Q. The first paragraph of that statement you quote -- indicates, "While we've concluded through our risk assessments that the maximum possible exposure to nitrosamines, which are also known environmental contaminants and found in water and foods, including meats, dairy products, and vegetables, in ARB medicines appears to be small, their presence in drug products is not acceptable."

You agree that the presence of NDMA or NDEA in drug products is not acceptable; right?

MR. INSOGNA: Form.

A. I wouldn't intentionally put that there.

BY MR. SLATER:

Q. From your perspective and in your opinion, it would never be acceptable to include NDMA or NDEA in the valsartan pills as we saw in this case; right?

MR. INSOGNA: Object to form.

A. I would answer it the same as before. I wouldn't put it there intentionally. It doesn't seem to have any benefit.

BY MR. SLATER:

Q. And it has risk; right?

MR. INSOGNA: Object to form.

A. Well, I think we'll get to that when we

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talk about my assessment of the literature that's available with respect to NDMA and other nitrosamines, in terms of what the risk is and what models that have been shown at what dose levels and for what duration.

BY MR. SLATER:

Q. At the outset when these pills were being sold and nobody knew the contamination was there, the patients were intended to take these pills for the rest of their life, likely; right?

MR. INSOGNA: Form.

A. Very often patients on blood pressure medicines are on those medications for longer periods of time.

BY MR. SLATER:

Q. If we look further down in that FDA statement, which carries over to Page 36.

This actually says in part, "The risk associated with abruptly discontinuing the use of these important medicines far outweighs the low risk that our scientists estimate to be associated with continuing the medicine until the patient's doctor or pharmacist provides a safer placement or a different treatment option."

Do you see that?

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A. Yes.

Q. So the FDA defined what it was speaking about as a low risk as being the low risk associated with continuing the medicine until the patient's doctor or pharmacist provides a safe replacement or a different treatment option.

That's how the low risk was defined; correct?

A. The risk was, as we talked about earlier, they were comparing risks of different things, and their statement there suggests that they felt that the risk of continuing the drugs is low, and that they should stay on the medication until a replacement could be found.

Q. They defined the low risk as the risk of continuing the medicine until the patient's doctor or pharmacist provides a safer placement or a different treatment option.

That's what the words state; correct?

A. Yes.

Q. At no point did the FDA say there's no risk from taking these pills; right?

A. No.

Q. It's not your -- rephrase.

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And certainly it's not your opinion there's no risk of taking these pills, right, on a prospective basis?

You're not saying there was no risk, you're quantifying the risk; right?

A. Yeah, quantifying the risk, and first started with their worst-case scenario risk, which is just on that same page a little lower down, where they make a lot of assumptions, which are all conservative assumptions, to say if patients were taking the highest levels found the whole time that this was the estimated risk to getting cancer over the period of time that they were taking it for the full time.

And so as you pointed -- as you asked me, the FDA did not say that there was zero risk, but they were showing that the risks were quite small even in the worst-case scenario.

MR. SLATER: Counsel, I think this is probably a good break point.

MR. INSOGNA: Okay. We can go off the record and talk about it.

MR. SLATER: Off the record.

THE VIDEOGRAPHER: We are going off the record -- I'm sorry. We're going off the record at

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2:50.
[A brief recess was taken.]
THE VIDEOGRAPHER: We're back on record at 3:06 PM.
BY MR. SLATER:
Q. Looking now at the bottom of Page 37 into 38. You referred to a table published on August 20, 2018, in an FDA communication.
Do you see that?
A. Yes.
Q. And you actually give some of the ranges of NDMA in certain foods; correct?
A. Yes.
[Discussion off the record.]
BY MR. SLATER:
Q. You list the NDMA levels per this table that's referenced for some food; correct?
A. Yes.
Q. Let's look at that. Cured meat. The figures are in micrograms.
Do you see that?
A. Yes, I do.
Q. If you want to convert that to nanograms, you would multiple by 1,000; right?

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A. Yes.
Q. So for example, for cured meat, in terms of nanograms it would be four to 230 nanograms; right?
A. Yes.
Q. With smoked meat, it would be four to 1,020 nanograms; right?
A. Yes.
MR. SLATER: Let's go off for a second, please. Can we please go off the record for a second, please?
THE REPORTER: Yeah. Michael?
THE VIDEOGRAPHER: We're going off the record at 3:08.
[Discussion off the record.]
THE VIDEOGRAPHER: We're back on the record at 3:09.
BY MR. SLATER:
Q. For grilled meat, it would be six to 130 nanograms; right?
A. Yes.
Q. For bacon, it would be 70 to 90 nanograms; right?
A. Yes.
Q. In terms of the levels seen in the

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valsartan pills of NDMA -- rephrase.
In terms of the levels of NDMA seen in the valsartan pills, starting with ZHP's manufactured valsartan, the levels are far higher in nanograms than what we see here for food; correct?
A. These are referenced levels that were in the FDA table, and I think when we get into the dietary studies, we'll see that many of the estimates are much, much higher than that.
So putting that into context, your question about these particular numbers and the ones in this table, the ones in this table are -- range between -- or the table above, that's saying what's the acceptable limit per day is 96 nanograms per day of NDMA. The same page.
Q. I'll try it again.
The levels of NDMA in these foods, as quoted in your report, are far lower than, for example, the levels seen in the valsartan manufactured by ZHP; correct?
A. Some are lower, yes. Some of the ones that were found that were tested didn't have any identified in the lot. Yeah, some were higher.
Q. We'll try it again.

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These levels of NDMA that you put into your report are far lower than the results of NDMA for the ZHP-manufactured valsartan; correct?
A. I think I answered and said that some are lower and some are higher, based on which lot and which pill, and that also these are not my -- this was quoted from the FDA website. This is what was put online.
In my report, I talk more extensively about diet and dietary studies, and trying to estimate various levels of NDMA, et cetera, and the limitations of doing that.
Q. Doctor, you put these figures in your report deliberately to help support your opinions, because you say right afterwards, "This table makes clear that NDMA exposure is a routine part of human life."
Right?
A. That was --
MR. INSOGNA: Object to form.
A. That was the point, was to show that we are exposed, as the FDA pointed out with some examples from one reference, of what we are exposed to just from a few different meats, for example.
This is not an exhaustive list of all the

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baseline exposure. The point was is that we are inundated with exogenous exposure to NDMA and other things like that on a daily basis. That was the point there.

BY MR. SLATER:

Q. So the point wasn't what you said in the report where you said, "This table makes clear that NDMA exposure is a routine part of human life. Indeed, as set forth below, estimates for total NDMA consumption often exceed the FDA's suggested acceptable intake"?

MR. INSOGNA: Objection.

BY MR. SLATER:

Q. That's what your report says is the reason why you put that -- those figures there.

Is that not true?

A. Exactly what I just said to you. I said -- the first sentence is that we are exposed to this routinely, and the second sentence as stated forth below in my report, when we talk about dietary exposure and other exposures, are routine and high -- much higher than the FDA's limit, which I also point out on the same page is 96 nanograms per day.

So I think we're agreeing.

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Q. In looking at the tables of the contamination levels that you put in your report, we had gone through earlier where it said -- we have Prinston Pharmaceutical, for example, which was ZHP, for the 320-milligram valsartan pills, in nanograms the NDMA level was 15,180 nanograms to 16,300 nanograms; right?

A. Yes, because those are in micrograms in the table, in that table on Page 35.

Q. The point I'm making is when we make them equivalent in terms of the measurement of nanograms, the levels of NDMA are massive compared to the levels in the foods as stated in your report; right?

MR. INSOGNA: Object to form.

A. No, I think I was qualifying that those foods were some examples that were pointed out by the FDA, but I've also in my same report lower down shown the wide range which is extremely higher than that on routine exposure through diet.

BY MR. SLATER:

Q. And many of the dietary studies that you talk about were performed at a time period before efforts were made to remove nitrates and NDMA from foods; right?

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A. Some of those papers are older, yes. Some are from this decade that are referenced.

Q. Did you make any effort to distinguish from study to study whether the dietary NDMA levels stated need to account for efforts by industry to remove nitrates and NDMA from foods?

A. I think as we get through it, there are a lot of limitations to these dietary studies in terms of trying to estimate. So -- I didn't hear if you said something.

Q. I told my dog to relax.

MR. INSOGNA: Continue your answer --

A. No, I lost --

BY MR. SLATER:

Q. I was muted so I didn't say it to you. I was on mute.

A. I was saying that there are many limitations to these dietary studies in terms of trying to come out with something that's robust. They have so many problems, they're very problematic in terms of looking at the question that I was asked to answer, which is do these levels in these pills increase the risk over what we're exposed to on a routine basis?

And so I think, as you saw in my report, I

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conclude that there are many dietary studies of which I discussed that are limited in their ability to help us with that question.

And so overall, I think the general opinion and takeaway from the dietary studies to me is that the overall exposure exogenously is much lower than endogenous production, orders of magnitude smaller, and that even looking at just the dietary studies alone, they're very problematic in terms of this particular question, looking at NDMA as opposed to they're looking at nitrosamines, nitrates, nitrates, which is not the same thing, obviously.

And so they're looking at surrogates of the question. And then to quantify how much people are taking, they're using questionnaires, which are notoriously limited in so many ways in being quantitative how much is actually going in, and so it's a surrogate of the reality.

And so you have to look at the data, which I did, but when I put it together and look at all the pieces of evidence in front of me in terms of the question I was asked, that is not a large component, or I don't put as much emphasis or weight on it as opposed to the human epi studies that have this exact same

question being assessed, which is patients taking valsartan with or without the impurity, which is a much more relevant question and more to point.

So yes, did I look at all the data? Yes. Did I assess the daily intake of diet in terms of a potential exposure to NDMA? Yes. And I explained to you how that relates to overall how I applied this to the question.

But ultimately when I look at the full dataset in totality, this is not as important to me as the human epi studies, which are in humans and looking at what they were exposed to, which is a question that I was asked to do.

So that's how I would answer the question about diet and the values that are here and comparing it to what's in the pills.

Q. Let's look on Page 38, Section 11, where you talk about the epidemiologic data.

Do you see that?

A. Yes.

Q. You state, "As set forth above, I have been asked to opine on whether there is sufficient data to support the conclusion advanced by some of the plaintiffs' experts in this litigation that, to a

reasonable degree of medical certainty, ingestion of NDMA at the trace levels detected in some valsartan drugs could have caused the cancers that the plaintiffs have alleged in this litigation."

I want to stop there. That's your summary of what the ultimate question was that you were evaluating; correct?

MR. INSOGNA: Form.

A. This was one of the questions that I was asked, yes.

BY MR. SLATER:

Q. When you refer to the cancers that the plaintiffs have alleged, are you talking about the plaintiffs who have been diagnosed with cancer who were saying that cancer was caused or contributed to by their intake of the contaminated valsartan?

A. Yes, it's the list of the cancers that were provided to me that have been included in this case.

Q. You state in the second paragraph that you placed the most weight on the epidemiologic data that actually studies the relationship between the exposure and the effect; right?

A. Yes, the human epidemiological data.

Q. And if I understand your methodology in terms of what you relied on -- we'll go through it in more detail step-by-step.

It's my understanding that you place the epi studies, the Pottegard and Gomm studies for people who are actually taking valsartan, at the top of what you -- your hierarchy of what you looked at here; correct?

A. Of all the available data, that is, yes, the top data, the most relevant data to the question that we're asking.

Q. You refer in the next paragraph, the third paragraph under Section 11, to less valuable dietary studies and animal studies, which you say are only weakly related to the inquiry at issue; right?

A. Yes.

Q. And again, that inquiry is what you referred to just above in terms of the question that you were looking at; right?

A. Yes, whether or not the impurities found in valsartan-containing drugs posed any increased risk.

Q. For the cancers alleged by the plaintiffs who claim that they have cancer in this case?

A. Yes.

Q. So let's start to walk through this a little bit. You talk -- rephrase.

Let's look at Section 11a. And you talk about the fact that there's two large cohort studies of people who fill prescriptions for valsartan produced by manufacturers in which the NDMA impurity was identified.

And again, that's the Pottegard and Gomm studies; correct?

A. Yes.

Q. Now, you say those studies compared individuals who took valsartan known or presumed to contain the NDMA impurity and individuals who took valsartan not believed to contain the impurity; right?

A. Yes, that was the general methodology of the study.

Q. Would you agree with me that there is uncertainty as to whether or not those assumptions are actually met as to all the study participants?

MR. INSOGNA: Object to form.

A. There's uncertainty with any assumption in any study, but I think it's a reasonable assumption that based on their tracking method in those national databases looking at the prescription level and

actually filling scripts -- I mean, they went through every step possible to minimize any error in that assumption.

BY MR. SLATER:

Q. Do you have the Pottegard study handy?

MR. INSOGNA: We can get it. Give us one moment, Adam.

MR. SLATER: Chris, you could mark the Pottegard study and just put it in, but I don't need to put it on the screen if the doctor has it.

MR. INSOGNA: What did you say?

A. 224. That's the reference in my paper.

Okay, I have it now in front of me.

BY MR. SLATER:

Q. Let's look now at the bottom of Page 38 where you talk about the Pottegard study.

A. Okay.

Q. You state that the study subjects were identified from the national Danish registry between September 2011 and June 2017; correct?

A. Yes.

Q. During that time period, was valsartan sold in this -- to these people who were being studied contaminated with NDMA and/or NDEA for that entire time

period?

MR. INSOGNA: Object to form.

A. I would have to review this, but I think that was what they started with, if you look at Figure 2 in the paper, and then based on inclusion of being eligible based on the criteria for the study, they excluded a number of patients, like patients who had previous cancer, et cetera, less than age 40, all that kind of stuff, and so it's not all of those patients that they identified that were in that range.

BY MR. SLATER:

Q. My question is different.

Did you evaluate whether or not valsartan sold between September 2011 and June 2017 was contaminated or whether it started to be contaminated later for some or all the manufacturers at issue?

MR. INSOGNA: Object to form.

A. I think that it was a date in 2012. And so the authors, if you look at their methods, they did a number of things to ensure accuracy here in terms of whether patients were taking the drug with or without a potential impurity, and also when they started.

They -- so for example, if a patient was on valsartan but not with a contaminated version, they

would be contributing follow-up time to the control arm, the control cohort. And only when they were -- they filled scripts that had the exposure or the putative exposure was when they then started contributing time to the cohort that had it, and so that they note there limits immortal time bias, and so it's a more accurate way of evaluating it.

And so to get to your question, they took into account when each patient would have started the actual drug with the impurity, even if they didn't start it right from the beginning of the timing of their study design.

Does that make sense?

BY MR. SLATER:

Q. Let me just be clear as to what you considered -- I forgot to cover this -- and then we'll come back to this study.

In terms of your methodology, my understanding is you looked at the epidemiology regarding valsartan specifically, and that's the Pottegard and Gomm studies. You also looked at dietary studies, you looked at industrial or occupational exposure studies, and you looked at animal studies.

Do I understand that correctly, and you

put that together, and that was what you considered in reaching your opinions?

A. Yes, as we talked at the very beginning, I also looked at the opinions of the plaintiff experts and what their opinions were and what they were relying on.

And then through my independent analysis, the way I normally do any scientific question, based on my experience, based on all my training on how to assess a scientific question and to review the literature, I then did exactly as you said.

I looked at the human epi, which I put at the highest priority, since we're humans; and then other ancillary support, which includes, as you pointed out, the occupational exposures, which again are surrogates of NDMA through occupations.

And then I'm sure we'll get to that, but sort of not asking the direct question, as an oral exposure but rather an inhaled, and then also the dietary. We've talked about the limitations of those. And then the animal studies, and we haven't really pointed to that yet, but taking all of that into account.

And again, using the human epi, these

studies here, as sort of the more weighted part of my analysis, since they're actually asking the question that I think we're all interested in, whereas all those other studies are looking at surrogate questions using surrogate assessments and estimations of exposure, so they're far lower on the hierarchy of the evidence to be used in such a case as this than the actual question at hand, which we had two human epi data studies, which are the two that we've been talking about.

And I'm happy to answer any other questions about it, but that's why I started with this and focused on this.

Q. I want -- let me ask the question again, because there's a lot you put in there that I tried to keep -- I didn't ask about. So let's go to my question.

I looked at your report. I looked at what you took into account. I saw you evaluating the human epi studies, specifically Pottegard and Gomm. You went through dietary studies. You looked at industrial/occupational exposure, and you looked at animal studies.

And that was the universe that you evaluated in terms of data to come up with your

opinions; correct?

A. Yes.

Q. And if I understand correctly, going a step further, you basically did an analysis of the weight of the evidence and put it all together to form your opinion; correct?

MR. INSOGNA: Object to form.

A. Yeah, I looked at all of the evidence and the pieces of the evidence from those various categories, some pieces being much larger parts of the puzzle, other pieces being much smaller parts but still considered, and ultimately came to my opinion based on the results.

BY MR. SLATER:

Q. When you talk about what you focused on the most, that was again Pottegard and Gomm, which you felt were on a much higher level and much different from the rest of the evidence available; correct?

A. Yes, for the reasons that I stated, since they're much more relevant studies for the question at hand.

Q. Do you know if the -- I'm coming -- rephrase. I'm going back to Pottegard now.

Do you know if the contamination levels in

the various pills varied over the years at all?

A. The contamination levels varied by lot over the years and by different company, according to the FDA reports and the tables that are shown there. They were not consistent.

Q. Was the variation in the impurity levels taken into account in Pottegard?

A. In a way, yes, because patients were doing what was the reality, which was they were being exposed to the question at hand, which is intermittent exposure that more likely than not wasn't the highest level in every patient for the whole time; which as we then point out from the FDA's assessments, they were always taking the worst-case scenario just to show that even that was a minimal risk, but the more likely scenario is that most patients weren't exposed to the highest levels, and certainly not for every lot throughout the duration of time.

And so in a way, Pottegard exactly accounts for that because it's the exact reality of what was going on. So it's looking at the question we're asking, not a hypothetical one of what if somebody had the whole thing the whole time at the highest dose, which we've all agreed is extremely

unlikely.

Q. You state in your report at the bottom of Page 38, "No statistically significant associations were reported between valsartan products potentially containing NDMA and any type of cancer."

And then you refer to the primary endpoint; correct?

A. Yes. Yes.

Q. The fact that there were no statistically significant associations between valsartan products potentially containing NDMA and any type of cancer -- why was that significant to you?

A. Because that's the question that I was asked to assess, is that if there is an added risk, which would be manifested by observing higher incidences of cancer in the patients exposed to it compared to those not.

So with this assessment, which was the primary endpoint, looking at any cancer, the answer was no. That's probably the most important piece of evidence of all the things considered, since it's the exact question we're asking.

Q. You then state at the top of Page 39, "In subgroup secondary analyses by cancer type, there was

no individual cancer that had a statistically significant association of valsartan products potentially containing the NDMA impurity."

Why did -- why was that significant to you?

A. Because as secondary analyses, we're interested, of course, in are there specific cancers that may or may not be associated with taking these agents versus the agents without the impurity.

And so it's secondary because it's not the primary analysis, it's not statistically designed to answer that question definitively, but it's looking at it because we have the data and potentially making sure that there's no subgroup that might have some association.

And in this case, that was not the case in this particular study.

Q. Did you independently verify the statistical analysis in Pottegard or any other study?

MR. INSOGNA: Object to form.

A. I didn't do any statistical analyses. I can read a paper and understand what the statistics mean, but I didn't confirm them or do any statistical analyses.

BY MR. SLATER:

Q. And you're not a biostatistician? You don't hold yourself out as an expert in biostatistics, do you?

A. I have been trained in biostatistics, I have a master's degree in it, but I don't hold myself as a statistician. I can understand them. It's the language that we speak in science, which is statistics, to ask questions or hypotheses and determine if there are -- the hypothesis can be accepted or not, as we talked about earlier.

So -- but I don't hold myself out to be a statistician.

Q. And again, you accepted the statistical analyses in these studies? You didn't independently verify; correct?

A. Correct.

Q. If there had been a statistically significant association either to any cancer in general or to a specific cancer, would that have been of significance to you?

A. In a hypothetical world, if the primary endpoint showed that there was a significant correlation in all cancers, then that would be

important data to consider from human epi data from the study.

In terms of the subgroups now, looking at them, when you see -- if you were to see a subgroup that showed a signal, we have to be cautious there. And I think we get to that in the Gomm study, where -- there's a concept called multiple testing in statistics, where if you test things enough and you slice the data enough and what might be referred to as massaging the data to look at it in various ways, eventually you may find something by chance.

And so that's exactly what a P value actually is, in a sense, where we talk about a P value of .05, in terms of what's statistically significant. And so that's translated to what you're more familiar with, is if it crosses one or not, a hazard ratio or odds ratio or relative risk.

If it's crosses one, then it's not statistically significant, and the P value is above .5. And if it doesn't cross the one boundary, then it is considered statistically significant, and the P value is less than .05. But all that's saying is that you may have a false positive, but it's a less than five percent chance that it's false positive; okay?

One in 20, five percent of the -- so if you look at 20 hypotheses, you will find one by chance, by accident. That's what statistics is all about. And we're allowing for that when we're doing studies like this, and saying we're going to set the threshold at being less than .05.

If we find an association, it's probably real, but there's a five percent chance that it's false positive. But then if you start looking at 20 different hypotheses, you're at risk of then really finding something that's false positive.

So getting back to the subgroups now, if I find an association in one of the many things I've looked at, then you have to look at that a little bit skeptical. And you note it, it's there, yet it's not something that's definitive, and that would probably require further independent validation in other cohorts in other studies before one would just hang their hat on that one finding.

So that's the difference with sort of looking at the main question and then looking at a whole bunch of subgroup analyses afterwards.

Q. So you're saying the subgroup -- rephrase.

Are you saying the subgroup analyses

shouldn't be considered?
A. I don't think I said that. I said that their value and your ability to put as much weight on the finding is lower.
And as an example, in many studies that look at a primary endpoint -- in many of my studies, their treatment and trying to improve survival -- and let's say the study is negative, this drug X doesn't improve survival in everybody enrolled; but in other analyses of man versus female, people above 60 versus less than 60, all kinds of different ways of looking at the people differently, are there difference among subgroups.
Sometimes there's one value or two that showed that the drug worked, and so we'll look at that and we'll say, "That's interesting, maybe the drug works in just a subgroup of people," but we also say this is a subgroup analysis, and it's at risk for false positives, and that we'd have to test this independently prospectively, that question and that tumor type, to be -- to have any weight or to hang your hat on that finding, so to speak.
And so we consider it, yes, we note it, yes, but we wouldn't act on it per se as much as we

would a primary endpoint of the same study.
Q. You pointed out with regard to Pottegard that on the subgroup secondary analyses by cancer type there was no statistically significant association.
You were stating that as part of the evidence that you're relying on to say that the NDMA in these pills, in your opinion, likely didn't increase the risk to the people that got cancer and are now saying they got cancer from the pills; right?
MR. INSOGNA: Object to form.
A. That's right. And remember, we go back --
BY MR. SLATER:
Q. That's right. That's all I asked you, though, Doctor. I literally just asked you yes or no. You confirmed it. I didn't ask for an explanation.
A. Okay.
Q. Now, in looking at this -- actually, let me find my note. One second.
Looking now at Pottegard, were there trends towards statistically significant association for any cancers?
A. I'm just looking at it real quick.
There were -- if you're looking at actual cancers, there were -- when you looked at subgroups,

your question is as opposed to all cancers, there was essentially no trend. It was like one, 1.09. It's essentially no difference.
But if you're looking at subgroups of cancers, you can see that some cancers look to the left of the force plot in Figure 3 of that paper, which suggest that it was protective, it was protective of taking these drugs compared to not taking impurity, and in other cancers there were trends the other direction which suggested that it was -- that it was consistent with an association.
And so the answer is yes, there were trends both ways. Trends means by definition in statistics not statistically significant, but trends towards one way or the other.
Q. First let's define for which cancers there were trends towards statistical significance.
One would be colorectal cancer; right?
A. Colorectal cancer was 1.46 trend to the right we would say on a force plot, but also the lower boundary was .79, the other side of one.
Q. Am I correct that there was a trend towards significance for colorectal cancer?
A. Depends on what you define as trend.

Often we define trend as it trends towards one way with a higher ratio, relative risk, and that the P value approaches .05, like maybe it's .06 or .07 or .08, not if it's .2 or .3 and it trends to that side from the hazard ratio.
So can you clarify what you mean by trend? Because this is not trending statistically. .79 is a very low bar, low boundary. It's not .98 as the lower bound or .99 as the lower bound. It's .79.
Q. Does the hazard ratio of 1.46 hold any significance?
A. It's the point estimate hazard ratio, meaning that's the point estimate of the 51 patients that were -- that had events with colorectal cancer.
Q. Was there a trend towards statistical significance for uterine cancer?
A. Uterine cancer you can see was 1.81 hazard ratio as a point estimate with confidence interval of .55 to 5.9 with 15 events.
The way I interpret that is that's not a statistical trend. That's spurious with wide range, wide confidence intervals with very few events.
Q. One second. In the abstract -- we'll just go with that, because it's just easier to focus on, on

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the front page of the article.
In the results section, the authors discuss what we just talked about, and they say, "For single cancer outcomes, increases in risk were observed for colorectal cancer, hazard ratio 1.46, 95 percent confidence interval, 0.79 to 2.73, and for uterine cancer, 1.81, 0.55 to 5.90, although with wide confidence intervals that included the null."
That's what we just discussed; correct?
A. Yes.
Q. Turn if you could now to the fourth page of the article.
A. Page 4?
Q. I don't have the page numbers on my copy. I'm just not seeing them. So it's the fourth page, though. It has -- the discussion starts on this page.
A. Yes.
Q. And they discuss the single cancer outcomes again.
You see that in the left-hand column; right? Right under Figure 2.
A. Which figure?
Q. Figure 2.
A. Figure 2? The flow chart of cohort

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selection of Danish users?
Q. Yes.
A. Yes. Okay, I see that.
Q. Right under that, it talks again about what we just discussed, the increased risks seen for certain single cancer outcomes; right?
A. It says that, and it says also did not reach statistical significance, yes.
Q. Right. They said increased risks were seen, but did not reach statistical significance?
A. That's how they worded it, yes.
Q. The next paragraph, they say, "Results comparable to the main analyses were found when we stratified by sex and age, whereas a stronger association was seen when we restricted to incident users during the study period, hazard ratio 1.58, 95 percent confidence interval, 0.99 to 2.52, compared with prevalent users at the beginning of the study period."
0.91 was the hazard ratio. 0.66 to 1.25, and that's reflected in Figure 4.
Do you see that?
A. Yes, I do.
Q. Did you understand the difference between

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a prevalent user and an incident user?
A. I believe a prevalent user was one who started on blood pressure -- who were on the valsartan at the time of the starting dates, as opposed to an incident user who started at some point later.
Q. And a prevalent user could have been on the medication and then could have stopped a week after the study period was established; right?
A. No, that doesn't sound right. It's -- patients who were taking the medications for the duration that they were taking them were included. So patient time and follow-up, what you see there, incorporates how long a patient was on the drug or not. All prevalent -- incidences -- who was on it to begin with versus not.
Q. Right. A prevalent user was someone who was already using the medication before the study period began; right?
A. And were on it at the beginning of the study period, yes. That's --
Q. Right. And then --
A. Yeah.
Q. Right. And then could have stopped taking the medication shortly thereafter; right?

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A. Some could, but they would be censored in terms of their follow-up after that point in terms of patient follow-up usage of the drug.
Q. What do you mean, censored?
A. Like they would be -- they would have accounted for the time they were on the drug, and then they would follow them for any incident cancers, but they wouldn't say that they were on it for the duration of the cohort time. For --
Q. Well, the study didn't require somebody to stay on the drug for the entire cohort time, it just required that they fill a prescription during the study period, one prescription; right?
A. Right. And the same thing could be for the incident user who could have started three weeks into the cohort and then stopped three weeks later. I mean, that argument would apply to either group that you just said.
Q. Did you discuss this analysis that I just read to you where the lower bound was 0.99? And that's -- if it was one, you would say this was statistically significant; right?
MR. INSOGNA: Object to form. Compound.
A. Well, I think this gets to the question of

multiple testing, multiple hypothesis testing, where if you're looking at all of these questions you're asking, you've asked many questions now, and so that is why this has much less weight compared to the original question of the main -- of all cancers.

But did I talk about every one of these in the paper? No. I think I summarized and said that overall that there was no difference in the main analysis, and that in secondary analyses that there was no statistically significant association.

I mean, I didn't pick out each one individually, though. No.

BY MR. SLATER:

Q. You didn't analyze this part of the study at all in your report? It's not mentioned; right?

MR. INSOGNA: Object to form.

A. I just mentioned that all secondary analyses done were not statistically significant, which sort of encompasses all of those subgroups in Figure 3 and 4.

BY MR. SLATER:

Q. If 0.99 at the lower bound of this confidence interval had come out as 1.00, would you have then talked about it?

MR. INSOGNA: Object to form. Assumes facts.

A. You know, in that hypothetical scenario, which I think there is one such like that in Gomm, I did point it out, as did the authors, to point out that there was a statistical finding, and we're going to get to that, I am sure, about one of the subgroup studies.

But I guess -- I think bringing you back to how statistics works is that yeah, if you keep looking at things, you'll find something, and you have to be cautious that it's just by chance.

And so overall in this particular paper, which you're asking me about, which I wrote about, there is no statistical significant one, and that's what I said, period.

BY MR. SLATER:

Q. So you thought it was important that there was no statistically significant outcomes either in the primary or secondary analyses; right?

MR. INSOGNA: Form.

A. That was an important finding because, remember, my question is when I'm looking at the hypothesis, which is these drugs increase cancer risk, the null analysis is that they don't, and the

alternative hypothesis is that they do, and so I need to look at data to be able to reject the null hypothesis and accept the alternative.

And what that means is is there a statistically significant finding in my main question or not, which there was not, and we will entertain subgroups to see if there are signals that maybe should be followed up on in future analyses, et cetera.

And in this case, there was no statistically significant signal -- any of the subgroups analyzed.

BY MR. SLATER:

Q. Would you agree with me that the follow-up period was too short to draw any definite conclusions?

MR. INSOGNA: Object to form.

A. I think that the conclusions of the authors are appropriate, which is -- and the limitations that they note are that at the time of the study, which was the follow-up that they were able to have, given this was relatively recent, was assessing what the risk is after this much time, which is I think very relevant to the questions being asked of us, because this is the time point at which plaintiffs are alleging their cancer is being caused by this. So it's

very relevant.

But at the same time, there are limitations to suggest -- and may point out here we don't know what this means from a longer perspective, we have to follow this longer.

BY MR. SLATER:

Q. So is the answer to my question yes?

MR. INSOGNA: Object to form.

A. Can you state the question again, please?

BY MR. SLATER:

Q. Would you agree that the follow-up period was too short to draw any definite conclusions?

A. Based -- about what question? About the question is there short-term risk? No, there's adequate follow-up. We looked at it. There was no short-term risk. This is what the cases are being asked of us at the moment.

Is it adequate to ask the question about longer term, 10, 15, 20 years later? No, of course not. We didn't follow them that long.

Q. For what carcinogens would you expect to see a signal in a cohort study conducted about four years after exposure?

A. Not many, in fact. It depends on the

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dose, and it depends on the duration that they're taking it, of course. But I think based on many of our reports that you've seen, you understand that the carcinogenesis of cancer, which is why I went into that as a background, is it takes decades at the time of the initiation of a cancer to the time it manifests.

And so right, an exposure, only three to four years of follow-up from that exposure, if the alleged risk is that it causes the cancer and starts it, then it would be very implausible, especially at these trace levels that we're talking about here. We're not talking about astronomical doses.

Q. Even with these what you call not astronomical doses, and even with this short-term follow-up period, increase in risk was seen for certain specific cancers; right?

A. -- human epi data?

Q. We went through this already. The colorectal cancer and uterine cancer, for example, showed increased risk; right?

A. Nonstatistically increased risk that are random variation from looking at subgroups -- a small number. Yes.

Q. Doctor -- I've really tried to be patient.

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I'd appreciate if you just answer my question. I didn't ask you about -- you keep throwing in things I'm not asking about. Your -- the lawyer sitting next to you can question you to his heart's content when I'm done.

MR. INSOGNA: Adam, that's absolutely not accurate. He responded to your question. That you don't like the answer does not mean it was not an answer.

MR. SLATER: Okay.

BY MR. SLATER:

Q. With what you just termed not astronomical doses of NDMA, we still saw increase in risk as reflected in the article for at least colorectal cancer and uterine cancer, as discussed in the abstract?

That's what the words in the study say; correct?

A. The words in the study say a nonstatistically increase in risk, yes. That's all I said when I responded.

Q. Looking at the conclusion, the authors state, "The results do not imply a markedly increased short-term overall risk of cancer in users of valsartan contaminated with NDMA. However, uncertainty persists

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about single cancer outcomes and studies with longer follow-up are needed to assess long-term cancer risk."

Do you agree with that description?

A. Yes. Yes.

Q. When they refer to uncertainty persists about single cancer outcomes, that means that this study certainly does not rule out a causal association; right?

MR. INSOGNA: Object to form.

A. That would be a correct interpretation, that it doesn't -- it doesn't rule it out that there's a causation, but it doesn't -- certainly doesn't rule it in any way. If anything, the evidence suggests against.

BY MR. SLATER:

Q. If you could look in the introduction of the study, just a little further down from we were just reading in that right-hand column of the first page of the article.

A. Yes.

Q. The second paragraph, the second sentence says, "NDMA is one of the most well-characterized and most potent animal carcinogens known." I want to stop there.

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Do you agree with that statement?

A. It doesn't say anything about the dosing and stuff, but we know that at very high doses it does cause cancers in various models like rats, yes. Way --

Q. I'll try again.

A. Way higher than the doses that we're talking about here.

Q. Yeah, but that's not what I asked you, so let's try it again.

This says in the second paragraph under the introduction, "NDMA is one of the most well-characterized and most potent animal carcinogens known."

Do you agree with that statement?

MR. INSOGNA: Object to form. Asked and answered.

A. I answered it with the qualification, but it does say that right there, yes.

BY MR. SLATER:

Q. And you agree with it? It's a true statement; right?

MR. INSOGNA: Same objection.

A. With the qualifications, because just agreeing to that statement can be very misleading.

BY MR. SLATER:
Q. Do you think this article is misleading?
A. I think that that statement without qualifying that can be very misleading.
Q. Is it scientifically accepted in the scientific community that NDMA is one of the most well-characterized and most potent animal carcinogens known?
A. At high doses, no.
Q. You're saying no, that's not understood in the scientific community?
A. No, excuse me. At high doses, that is accepted, yes. That it's a potent carcinogen at very high doses.
Q. So you think at low doses NDMA is not considered a potent carcinogen?
A. No. We can talk about that, but you can see it in all the datasets that in some -- in some studies, the control are not getting any NDMA to have more cancers than at the low doses.
So in other words, no, it's not potent at all at low doses.
Q. Which study is that?
A. The Keto (ph) studies, for example, are

probably the ones fresh in my mind.
Q. This says in the second paragraph under the introduction, "NDMA is one of the most well-characterized and most potent animal carcinogens known and has been shown to be a potent carcinogen across all species that have been investigated, both as single doses and with long-term exposure to lower quantities."
Do you see that statement?
A. At single doses, yes. I think we'll be talking about astronomically high doses of that agent.
Q. Doctor, all I asked you is if you saw the statement.
A. I saw the statement, yes.
Q. So why -- I don't understand why you're arguing something I didn't even ask you.
A. You asked if I agreed with it.
Q. No, I didn't.
MR. INSOGNA: You don't need to argue -- there's no --
BY MR. SLATER:
Q. Actually, all I said was do you see that statement.
A. I see the statement.

Q. It's a true statement; correct?
MR. INSOGNA: Object to form.
A. With the qualifications that I mentioned. It can be toxic at very high single doses, yes, which is not relevant to what I've been asked to opine on here.
BY MR. SLATER:
Q. I'd have to ask you again. I mean, Doctor, just --
MR. SLATER: We're never getting done today. I can tell you that right now, counsel. I'm going to end up having to continue through tomorrow. We're going to have to figure out a time, because I'm just not getting anywhere now. And it's been going on for hours.
MR. INSOGNA: He is answering your questions. You just don't like the answers. You --
MR. SLATER: Counsel, I don't like when people say you don't like the answer. It's not a question of liking or not liking the answer. I'd prefer it just be responsive. That's all I'm asking.
MR. INSOGNA: I think he's answered --
MR. SLATER: I've been very patient, unbelievably patient through this deposition. I'll

continue to be so. But if I ask a straightforward question and the witness continually provides disclaimers and explanations rather than a yes or a no, then I have to just keep coming back.
This is an expert. This isn't some regular layperson witness. We need to be able to proceed in an orderly way.
MR. INSOGNA: Ask your question.
BY MR. SLATER:
Q. This states in the second paragraph under the introduction, "NDMA is one of the most well-characterized and most potent animal carcinogens known and has been shown to be a potent carcinogen across all species that have been investigated, both as single doses and with long-term exposure to lower quantities."
That statement is found in a study that you're relying on heavily for your opinion in this case; correct?
MR. INSOGNA: Object to form.
A. The reference there to Number 5 is not to the Keto study that I just mentioned. If that's your question, no.
BY MR. SLATER:

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Q. I'm talking about this study, the Pottegard study that we're asking about.
That's the one you're relying on heavily; right?
A. Oh, for the human epidemiological data? Yes. I thought you were talking about that sentence that has Reference 5 to the -- and you were insinuating it was to the data I was relying on for animal data. It's not.
Q. I actually wasn't insinuating that. With re -- I'll do it again.
In the introduction, right-hand column, second paragraph, it says in part, "NDMA is one of the most well-characterized and most potent animal carcinogens known and has been shown to be a potent carcinogen across all species that have been investigated, both as single doses and with long-term exposure to lower quantities."
That statement is found here in the Pottegard study, which you're relying on heavily for your opinion; correct?
A. I'm relying on the results of the study, yes, not that statement in the introduction, no.
Q. It continues, "Although no in vivo data

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are available for humans, NDMA seems to be metabolized similarly in human tissue and rodent tissue."
That is also stated; correct?
A. Yes.
Q. You don't disagree with that; right?
A. Not necessarily.
Q. Let's go back where we were talking just before about incident users versus prevalent users, just above the discussion section; okay?
A. Yes.
Q. If the lower range of that analysis had been 1.01 instead of .99, that would have achieved statistical significance; correct?
A. That is a correct statement.
Q. So would it be fair to say that for incident users, people who started taking the drug during the time in question, there was almost a 60 percent increased rate of cancer, and this almost reached statistical significance?
A. Almost reached statistical significance would be an appropriate summary, yes.
Q. Let's go, if we could, to the sixth page of the article, the principal findings.
A. Yes.

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Q. The principal findings starts out, "Our estimates pertain to early cancer risk associated with exposure to NDMA through contaminated valsartan products and should not be interpreted as evidence against NDMA being carcinogenic to humans in general. At most, our findings suggest that the level of NDMA exposure achieved through valsartan products do not translate into a substantially increased short-term cancer risk."
Do you see what I just read?
A. Yes.
Q. Did you anywhere in your report reference or comment on what I just read?
A. I believe so, yes.
Q. Or to Pottegard?
A. Yes.
Q. Where?
A. When I -- on Page 40 at the top of my report, the first sentence. "While each of these studies notes the obvious limitation of a shortened follow-up period" -- the period is actually more closely reflective to what we're talking about now, which I also said a few questions ago as well.
Q. Did you say in your report that the

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results of this study should not be interpreted as evidence against NDMA being carcinogenic to humans in general?
A. I didn't say that, no.
Q. And you would agree with me that the results of this study should not be interpreted as evidence against NDMA being carcinogenic to humans in general?
You would agree with that; right?
A. With long-term follow --
MR. INSOGNA: Object to form.
A. With long-term follow-up, I agree with that, yes. You had asked the question with respect to the follow-up that it did do, which is relevant to current cases I've mentioned.
BY MR. SLATER:
Q. Going down to the bottom of that paragraph. They talk about the single cancer outcomes, in particular colorectal and uterine cancer, and they say that, "This clearly highlights that our study cannot confidently rule out an increased risk from exposure to NDMA."
Correct?
A. Yes, they say that.

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Q. And you agree with that; right?
A. Yeah, I think that that's a very fair statement, as we've been saying, is that these data that we're looking at subgroups are exactly that. They're subgroup analyses looking at smaller subsets.
There's no obvious or large -- which I think they also point out throughout this paper and the other paper -- that there's no obvious and large magnitude benefit -- or effect, excuse me, but that smaller effect sizes, and because these are subgroups, we can't rule out a possible association, but there's no evidence from these data that there is.
Q. Further down in the second paragraph under the principal findings, the authors refer to the uncertainty about the actual NDMA content of valsartan products.
Do you see that?
A. I remember reading about that. Where did we -- where is that again?
Q. It's four lines up from the bottom of the page.
A. Yes.
Q. That uncertainty about the actual NDMA content of the valsartan products that the people in

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this study took has to raise some questions; correct?
MR. INSOGNA: Object to form.
A. It's a known limitation, in that despite all efforts that were made to try and quantify that was being done and what patients were getting what and when, there was always the possibility that -- I mean, especially in a group that was classified as possible as opposed to probable -- that they may not, but there were sensitivity analyses in these studies to sort of address that by excluding the ones that were possible and looking at just those that are probable.
There were other sensitivity analyses that cut off the date from if they were only on it for one year to six months or two years, to see if there were any major differences. So those types of sensitivity analyses that are done in these studies are trying to assess some of the limitations to make sure that there isn't something being missed, to the best of one's ability.
But despite that, to your question, that they're noting here appropriately that there's still going to be some uncertainty, like there is with any study of its kind like this.
BY MR. SLATER:

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Q. The people that they assumed were probably exposed to NDMA were those who took a product that was manufactured by ZHP at some point; right?
A. I believe so. I'd have to confirm that here again, but that sounds very familiar, yes.
Q. And that means that somebody could have filled one prescription of ZHP-manufactured valsartan and then taken pills manufactured by other manufacturers the entire rest of the study, but they would end up in the side of the study that's assumed to have been exposed to NDMA; right?
MR. INSOGNA: Form.
A. I think we talked about that earlier. I think that they had to -- they were trying to reflect what was happening in reality; and that the likelihood, as you point out very well, is that a given patient is very unlikely to have been unlucky to have gone a lot with the highest levels the whole time.
But if that happened, they would be included here, but to the extent that it did happen, this was reflecting what was actually happening. So this asks the question that's very relevant to us, is do patients who got some do worse than those who didn't.

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BY MR. SLATER:
Q. So coming back to my question, which I'd appreciate if you could answer.
Somebody who was placed on the side of the study as having been assumed to be exposed to NDMA could have filled one prescription of ZHP valsartan one time, and then the rest of the study period taken valsartan manufactured by manufacturers that did not have NDMA contamination, but that person would be on the NDMA side of the study; correct?
MR. INSOGNA: Object to form.
A. They would have to be, because now they've had exposure to the putative exposure. So yeah.
BY MR. SLATER:
Q. So the answer to my question is yes?
A. Yes, patients who were exposed to the probable or possible were then included in that group, because they were in that group.
Q. You would agree that somebody who took one prescription of ZHP valsartan that was contaminated with NDMA would have received a lower dose than somebody who filled prescriptions of ZHP valsartan, let's say, for two full years; right?
A. In the main analysis they did that. They

lumped them together as being exposed. But if you read on Page 2 in the methods on the right, it said they further stratified by the time of cumulative dose of these filled prescriptions with NDMA and put them into categories based on the amounts that they were exposed to. So they tried to account for what you're getting at, basically.

And then if you look at Table 2, they're looking at by that cumulative exposure, which is assessing exactly what you're asking, to say if people that were on more did worse than those who didn't, which was not the case.

Q. You're saying people who took the medication for a longer period of time; right?

A. For more cumulative exposure to the NDMA exposed lots. That's less than 20,000, greater than 50,000, or in between. Those are the three categories. So they are accounting for what you're asking about.

And you can see on the right there, especially after when you look at all the adjustments that they did that there's no difference between those who got less versus more versus intermediate, in terms of their assessment, in terms of hazard ratio. All of them cross one, one of them is actually lower than one,

and the effect sizes, the point estimates, are 1.15, 1.11.

Q. Are you suggesting that they went through every single prescription filled by each person and stratified based on an analysis of every single prescription for each person?

A. If you read this page, that they said they further stratified exposed person time by cumulative dose from filled prescriptions of potentially NDMA-containing valsartan tablets.

So the answer to that is they made an attempt to do that at every prescription. That was the strength of the study, is that they have the records of when people went and picked up their scripts.

Q. When they did so, did they distinguish between whether or not the pills were manufactured by ZHP, if somebody was in the assumed NDMA-contaminated part of the study, or did they just go by the overall filled prescriptions without analysis of whether it was ZHP or not in every single prescription?

MR. INSOGNA: Object to form.

A. The answer to your question is earlier in that same paragraph, where it says that they were able to identify 128 unique drug products that were

identified to be manufactured by ZHP, and so they were able to classify by that, versus if you read the next sentence it talks about other products that were classified as possibly contaminated, and they had ZHP and other companies.

And so they categorized by those two main categories or not, those three subgroups.

BY MR. SLATER:

Q. But again -- but again, when doing the stratification, they didn't go prescription by prescription, say ZHP, not ZHP? They didn't do that analysis; correct?

If you were in the ZHP side of the study, meaning you filled one prescription, that's how you got in and that's how you were analyzed; right?

A. In the all-comer group, yes, that's how they were analyzed, but when they were looking at Table 2 they were looking at -- you could see a never-user or an ever-exposure, the top two rows.

But then they're looking at the cumulative exposure by looking at the amount that they actually were exposed to.

Q. Well, they have no idea what they were exposed to? They don't have the exposures levels lot

by lot, so there's no way for them to know that; correct?

MR. INSOGNA: Object to form.

A. They're looking at the estimated by the pills here, further down in the same methods, where they were estimating based upon the amount of -- the drug amounts that they were taking.

BY MR. SLATER:

Q. So if somebody only filled one prescription of ZHP and then took other manufacturers that were uncontaminated, you're saying that they only counted for that person the one prescription of ZHP, even though they were on the presumed contaminated side of the study?

MR. INSOGNA: Object to form.

BY MR. SLATER:

Q. Because I didn't see that they did the analysis to that level of granularity. I thought that once you got on that side, you were analyzed as you were exposed to contaminated pills.

A. I'm looking at this sentence, and the way I read it is we further stratified NDMA exposed person time by cumulative dose from filled prescriptions of potentially NDMA-containing valsartan tablets, which

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they knew because they filled the script and they were able to define which products were from ZHP.

So I read it as they would add up all of the ones that they took from that company, and if they met, then they would categorize them into those three groups.

And then the rows in Table 2, they looked at it whether they never used it versus used it, which was the main analysis; and then they looked at the cumulative exposure to the NDMA pills.

That's the way I look -- that's the way I see what they wrote here.

Q. It doesn't actually say that they did what you're saying? That's what you're assuming; correct?

MR. INSOGNA: Object to form.

A. That's how I read that -- I read that now, even -- that's how it reads to me. In a question like this, maybe I would look for a clarification.

BY MR. SLATER:

Q. Now looking at the top of that page where you were just reading, where they talked about the other side of the study, the other group which was the people they classified as unlikely to be contaminated with NDMA.

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You see that?

A. I'm sorry. Where?

Q. At the top of the second page of the study, the other side of the study, the people who were assumed not to have been taking valsartan --

A. Yes.

Q. -- that was contaminated with NDMA.

Those were people who took pills that were not manufactured by ZHP; correct?

A. In the never group, yes. Or from that second category, possibly, which included ZHP and they call it other companies, but that doesn't specify which companies.

Q. Well, if you took it from ZHP and another company, you ended up on the contaminated side of the study; right?

A. Yes. Yes.

Q. This side of the study, the never side of the study, included people who didn't take any ZHP-manufactured valsartan? That was that group; right?

A. Or the other companies, is the way that I read it, which is that intermediate group of possibly exposed. Because you read here on the same page, where

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it goes -- just one sentence before the one I quoted before, which is in the main analysis we pooled together prescriptions classified as probably and possibly contaminated as being those exposed, compared to of course those who weren't in those two groups.

And right before that, it's defining what those two groups are, and possibly included the ZHP and those from other companies.

Q. As long as they filled the ZHP prescription; right?

A. Or they fit into that category as defined here, yes.

Q. The other side of the study was people who did not take any ZHP; right?

A. And my understanding is -- or if those other companies that are listed in that possibly contaminated intermediate group.

Q. And where do you see that list?

A. The list?

Q. The list of the other companies that were considered to be contaminated. I didn't see such a list.

Who were you assuming -- where do you see that?

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A. I just see -- I'm just reading what they stated here, and that they say they included in that group of possibly contaminated those who contained an active pharmaceutical ingredient from both -- both from ZHP and from other companies.

Q. That's the -- all right. We're going in circles and circles here, and I think we're really struggling through something that should be really simple.

This says at the bottom left-hand corner of the second page that they identified those that were, quote/unquote, probably contaminated with NDMA, and then 36 additional products possibly contaminated with NDMA, as they contained an active ingredient, active pharmaceutical ingredient, both from ZHP and from other companies.

A. Right. Yes.

Q. So that would be someone like a Teva that was using ZHP's API and selling the product; right?

MR. INSOGNA: Object to form.

BY MR. SLATER:

Q. Or do you not know?

A. I don't know that.

Q. The other side of the study would not have

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been people who took ZHP valsartan at all; right?
A. Yes. I --
Q. Do you know which manufacturers are included in that other side of the study? Does it say? Because I don't see it.
A. It doesn't say.
Q. Did they analyze whether or not those other manufacturers were also selling valsartan contaminated with NDMA?
MR. INSOGNA: Object to form.
BY MR. SLATER:
Q. I don't see that either.
A. I don't see that on this particular paper either, no.
Q. In fact, it's possible that people on the -- what you termed the never side were taking pills contaminated with NDMA also? That's possible as well to some extent; right?
MR. INSOGNA: Form.
BY MR. SLATER:
Q. Because we know manufacturers other than ZHP were also manufacturing and selling contaminated valsartan in Europe at that time; right?
MR. INSOGNA: Object to form.

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A. I don't know the answer to that. It's possible if they didn't exclude them and they didn't know about it at the time, because this publication was in 2018 as opposed to the Gomm study which was later in 2021.
BY MR. SLATER:
Q. Well, did they talk about excluding any other manufacturers or identifying other manufacturers as having contaminated pills, or do they link only to ZHP here explicitly?
A. Looks like just to ZHP here.
Q. For example, in the never group, do you know when Torrent announced their contamination of their pills?
MR. INSOGNA: Object to form.
A. The date?
BY MR. SLATER:
Q. Yeah. Do you know if -- I'll ask it differently.
Do you know if Torrent announced their contamination before or after this study was published?
A. I don't know.
Q. I'm going to -- I'd like you to assume for purposes of this question that Torrent announced after

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the study was published that their pills were contaminated with NDMA. Okay? I'd just ask you to assume that.
A. That I'm assuming what? That it was done before?
Q. After.
A. They presented after the study --
Q. Let me ask it again.
I'd like you to assume that Torrent announced that its pills were contaminated with NDMA after this study was published.
A. That makes sense.
Q. Do you know whether Torrent's pills were contaminated?
A. There was -- yes, I think that's one on the list.
Q. In fact, Torrent was buying its valsartan API from ZHP.
Were you aware of that?
A. I think so, yes.
Q. And therefore, Torrent would have some of the highest levels of NDMA that we would see in this litigation, because it came from ZHP; right?
MR. INSOGNA: Object to form.

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A. Yes, and if they didn't account for that as being from ZHP, I don't know. It doesn't say in this paper.
BY MR. SLATER:
Q. So therefore, Torrent, since there was no announcement or knowledge that Torrent had contaminated valsartan, people who took Torrent valsartan would have ended up in the never group, based on this description of the study; right?
MR. INSOGNA: Object to form.
A. With that hypothesis, in that scenario, that if there were drugs that came out later after the study was done that ended up having also contaminants, and it wasn't already accounted for, then yes, they could have ended up in the control group of this particular study.
BY MR. SLATER:
Q. And that would be problematic in terms of the validity of the final results if you had highly contaminated valsartan being taken by people in the never group; right?
MR. INSOGNA: Form.
A. The results would be about ZHP compared to other compounds would hold and that there's no

difference in terms of their added risk, how I assess that.

MR. SLATER: Wait. Could I have that answer read back? I lost that.

[The requested portion of the transcript was read by the reporter.]

BY MR. SLATER:

Q. I don't think I understand.

If people who took Torrent valsartan that was contaminated with NDMA were included in the never group, that would be problematic in terms of the results of the study, in terms of comparing the two groups; right?

MR. INSOGNA: Object to form.

A. In that hypothetical scenario, which was not specified here that that's actually what happened, then if there were drugs in the control arm that had contaminant that wasn't accounted for, then that would be problematic in terms of the assessment being done, and it would bias towards the null.

BY MR. SLATER:

Q. What about Hetero? Do you know if Hetero was in the contaminated side of the group or the never group, in terms of people who took Hetero valsartan?

Do you know where they got grouped?

A. It seems like all the non-ZHP drugs would be grouped in the never.

Q. And we know that the Hetero valsartan was contaminated as well; correct?

A. Some lots.

Q. So that would be yet another point of uncertainty, where did the Hetero people end up and what was their level of contamination that they took; right?

MR. INSOGNA: Object to form.

A. In that scenario, if that was the case, yes.

BY MR. SLATER:

Q. Does this study grapple with this issue that we're talking about at all? Like do they analyze at all other manufacturers, how they determine whether other manufacturer's pills were contaminated?

Do they go into any of that at all?

A. They didn't, and the publication date of this is in 2018, like I mentioned. And so it may be, as I think you pointed out, that at the time that they were doing this study that it wasn't known.

Q. Did you ever look into determining --

MR. SLATER: Whoa. Whoa. Rosemarie, your phone just came on off of mute. You might want to put it back on mute. Thank you.

BY MR. SLATER:

Q. Did you ever make any effort to determine which manufacturer's valsartan was recalled in Europe after the Pottegard study?

Did you look into that?

A. I looked at the dates at which all of the different recalls were being done over the time after the initial one on the FDA website I saw. They have a similar website, the EMA.

Q. You would agree with me, based on the questioning that we've been going through for the last several minutes, that that would be something that would be very important to consider and understand; right?

MR. INSOGNA: Object to form.

A. It would be important to understand. In the end, though, when I was asked to opine on whether or not these trace levels in these drugs were associated with known risks for cancer based on the data, this was one of the studies, and it does not show that there is evidence of an association.

BY MR. SLATER:

Q. This study draws conclusions based upon a comparison of two groups of people, and based on an assumption that one group was probably or possibly exposed to contaminated valsartan and the other group was not?

That's where the data comes from, the comparison of the two groups; right?

A. Right.

Q. It's the base assumptions as to whether or not the people in the groups were exposed or not exposed to contaminated NDMA are not accurate, that would undercut the data completely; right?

MR. INSOGNA: Object to form.

A. But in that larger pool of patients getting the never, there are a number of companies that are not having the contaminant.

So even if there were -- after the fact that they learned that there were some companies that also did, then it would be a small subset of the whole of the nevers. It's not all of them, in other words.

So it's not enough to change the overall outcome per se until some dataset showed that. So in other words, it's an important point to consider, but

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it's not like that proves the alternative hypothesis in any way.
BY MR. SLATER:
Q. What it does, in fact, is presents an open question; correct?
MR. INSOGNA: Object to form.
A. An example of confounding, which is in a lot of association studies, that are despite all efforts, like in this case, it's an example of one that wasn't known to be adjusted for in the first place.
BY MR. SLATER:
Q. It's actually -- I don't mean to interrupt. I'm sorry.
A. And it's a risk of all of these types of studies, but again, this is the study most closely related to our question, and even with that potential confounder, it's a small subset of the nevers.
It's not all of them, in other words, whereas the ones that are classified in the known, probable, or possible, they are exposed. And so --
Q. How can you make --
A. -- two cohorts that are different.
Q. How can you make that statement when you have absolutely no idea as to whether or to what extent

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the people in the never group were taking contaminated valsartan also?
You don't have any idea how to quantify that, so you can't make the statement you just made; correct?
MR. INSOGNA: Object to form.
A. I'm stating that it's more likely than not not a large subset of that never group.
BY MR. SLATER:
Q. Well, what was the percentage of people in the never group that were taking contaminated valsartan?
Do you have any idea?
MR. INSOGNA: Object to form.
A. Now that probably could be assessed, because you could go back and look at this. But in the meantime, I would assume that they would be a small subgroup, because there were many agents out there that weren't contaminated, and the chance that everyone in the control group, in other words, got a contaminated pill is essentially zero.
BY MR. SLATER:
Q. How many of the people in the control group were exposed to contaminated valsartan?

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You have no idea; right? There's no way for you to have any idea on that; right?
MR. INSOGNA: Object to form.
A. I estimate that it's likely a low amount.
BY MR. SLATER:
Q. You estimated -- you have no way -- that's a guess, there's no basis for you to make that statement other than to guess; right?
MR. INSOGNA: Object to form.
A. Based on probability, I would say that it's a low likelihood.
BY MR. SLATER:
Q. Probability of what? Probability of biased speculation? Which I think I just made up that term, which I think you can -- you can use if you want. But -- and let me, without kidding around -- I'm trying -- obviously not trying to be funny.
But that sounds to me completely speculative, since you have absolutely no basis to know which manufacturers, what their contamination levels were, or how many took the pills from those manufacturers.
You don't have any of that data; right?
MR. INSOGNA: Objection. Argumentative.

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A. What I'm stating is that it's unlikely to be a large proportion of that group.
BY MR. SLATER:
Q. Based on what?
A. Chance.
Q. So you're just speculating?
MR. INSOGNA: Object to form.
A. You asked me to make an assessment of the quantity of patients.
BY MR. SLATER:
Q. What I think you said before is you could go do a follow-up study now. So in that context, my question is this.
As we look at Pottegard, there's a significant open question as to who on each side of the study took contaminated valsartan and to what extent, and you would need to do a subsequent follow-up study and reanalyze the data in order to get any sort of reasonable degree of medical certainty as to the answer to that question; correct?
MR. INSOGNA: Object to form. Compound, argumentative.
THE WITNESS: To be more precise, you would need the actual data, yes.

MR. INSOGNA: Adam, are you moving off of Pottegard now? We've been about an hour-and-a-half.

MR. SLATER: I was thinking about moving off of Pottegard, although I like saying Pottegard a lot. But -- so we can go off the record.

THE REPORTER: All right. One moment.

THE VIDEOGRAPHER: We are going off the record at 4:44 PM.

[A brief recess was taken.]

[Deposition adjourned until the following day.]

C E R T I F I C A T E

I, JOHN ARNDT, a Certified Shorthand Reporter and Certified Court Reporter, do hereby certify that prior to the commencement of the examination, DANIEL CATENACCI, M.D., was sworn by me via videoconference to testify the truth, the whole truth and nothing but the truth.

I DO FURTHER CERTIFY that the foregoing is a true and accurate transcript of the proceedings as taken stenographically by and before me at the time, place and on the date hereinbefore set forth.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in this action.

____

JOHN ARNDT, CSR, CCR, RDR, CRR

CSR No. 084-004605

CCR No. 1186

I, DANIEL CATENACCI, M.D., the witness herein, having read the foregoing testimony of the pages of this deposition, do hereby certify it to be a true and correct transcript, subject to the corrections, if any, shown on the attached page.

____

DANIEL CATENACCI, M.D.

Sworn and subscribed to before me,
This ________ day of __________, 202_.

____

Notary Public

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DANIEL CATENACCI, M.D.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	) MDL No. 2875
THIS DOCUMENT RELATES TO ALL CASES	)

CONFIDENTIAL INFORMATION - SUBJECT TO PROTECTIVE ORDER

VIDEO DEPOSITION OF DANIEL CATENACCI, M.D.

VIA VIDEOCONFERENCE

September 14, 2021

9:20 a.m.

Volume 2

Reporter: John Arndt, CSR, CCR, RDR, CRR
CSR No. 084-004605
CCR No. 1186

DEPOSITION OF DANIEL CATENACCI, M.D., produced, sworn, and examined via videoconference on September 14, 2021, in the City of Chicago, State of Illinois, before John Arndt, a Certified Shorthand Reporter and Certified Court Reporter.

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James Arndt (videographer)

INDEX OF INTERROGATION

INDEX OF EXHIBITS

(All exhibits are attached.)

THE VIDEOGRAPHER: We are back on the record for the continuation of the deposition of Daniel Catenacci, M.D. Today's date is September 14th, 2021, and the time is 12:09 PM Central Standard Time.

Counsel, please continue.

MR. SLATER: Thank you.

EXAMINATION

BY MR. SLATER:

Q. Hello, Doctor.

THE REPORTER: Oh, he's muted.

[Discussion off the record.]

[Exhibit 13 marked for identification.]

[Exhibit 14 marked for identification.]

BY MR. SLATER:

Q. Doctor, I'm going to start with some questions about the Gomm study, so if you have that handy, perhaps -- I assume you probably have it right in front of you.

A. Right where we left off, yes.

Q. Exactly. Okay. You speak on Page 39 about the Gomm study, which was published in 2021; right?

A. Yes.

Q. And looking at Page 357 of that article,

there is a statement in the right-hand column, first paragraph, right at the bottom of that paragraph that says NDMA is one of the most potent mutagenetic carcinogens in animal models. I'm going to stop there.

Do you agree with that statement?

A. I agree with it similarly to the other paper that this was pointed out, that it's carcinogenetic in high doses, yes, in models, in animal models.

Q. Has NDMA been shown to be mutagenetic in animal models where what you would term a high dose was not given to the animal?

A. I am not following the question.

Q. Is there any animal study you're aware of where cancer was caused to the animals by NDMA where a high dose, as you would define that term, was not given to the animal or a lower dose was given?

A. If I understand the question correctly -- say, for example, if we're looking at one cancer type, and so you're asking -- let's focus on liver cancer.

Are there models that show liver cancer at high doses? Yes. Like, for example, the rat model. But there are other models -- say, the nonhuman primates -- at high doses for NDMA that do not show

liver cancer, if that's the question.

Or is the question, are there models at low doses that show the same cancer?

Q. Let me ask it a little bit differently. The scientific consensus in the peer-reviewed literature is that NDMA is one of the most potent mutagenetic carcinogens in animal models.

Do you agree with that statement?

MR. INSOGNA: Object to form.

A. I agree with that with the understanding that that's not taking into account the dosing of it, and -- which is what is at play here in the question that I was asked --

BY MR. SLATER:

Q. So the peer-reviewed literature, in your opinion, is deficient because, for example, in this peer review article that you're relying on heavily, they don't point out that it has to be at very high doses, as you would term it, so all these articles are in error?

A. These are just incomplete sentences about the details of that statement. This is an introductory paper saying an overview of this topic, and it's -- but it's not going into the details of what that statement

means.

Q. So incomplete sentence after incomplete sentence exists across the literature in this area; right?

That's what your testimony is?

MR. INSOGNA: Object to form.

A. No, I'm trying to answer the question with the understanding that I wouldn't just give a blank approval to that statement without considering what I said -- the dose and the duration of that agent or any agent when talking about something like that.

BY MR. SLATER:

Q. You agree that NDMA is a mutagenetic carcinogen; correct?

A. In animal models at certain doses, it is and has been shown to be, yes.

Q. Go to Page 360, please. On the top right-hand column -- actually, the right-hand column in the middle of the page -- there's a heading that says regulatory and public health implications.

Do you see that?

A. Yes.

Q. And the authors state about halfway down that paragraph, "The immediate recall of all

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potentially NDMA-contaminated valsartan drug products by regulatory authorities worldwide was necessary in order to protect the public health."

Do you see that?

A. I see that sentence, yes.

Q. And that sentence was made in one of the two articles that you have already told us are the two most important pieces of literature in the scientific literature that you're relying on; right?

MR. INSOGNA: Object to form.

A. This statement is in those papers, and my -- are you asking me what the interpretation of this statement is?

BY MR. SLATER:

Q. No, I was asking you to confirm that that statement's found in the Gomm study, which was one of the two studies that you say you're relying on above all else, along with Pottegard?

MR. INSOGNA: Object to form.

A. This statement is in a paper that I relied on from the data to evaluate whether or not there was an increased risk in cancer from trace impurities in these drugs. This statement has no bearing on that assessment.

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BY MR. SLATER:

Q. Well, when the authors say that it was necessary in order to protect the public health, they're saying that because of the risk that the contamination with NDMA could cause cancer to humans, it was necessary to stop selling those contaminated pills; right?

MR. INSOGNA: Object to form.

A. My interpretation of this is to say that if there was a potential risk, it was necessary to evaluate whether there was or not and not continue to use those medications. That doesn't prove that there was an association or that these caused that. They're just stating that it was necessary to make an evaluation whether or not that that existed, and in their paper they conclude there is no association with cancer.

BY MR. SLATER:

Q. The regulatory authorities not only ordered the recall to protect the public health, but made a decision that pills with the levels of NDMA that were seen, certainly over 96 nanograms, should not be sold ever again; right?

MR. INSOGNA: Object to form.

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A. I think I answered that before, but I'll say that they made this recall to ensure there wasn't a risk, to evaluate if there was a risk, and during that time to not continue giving the medications.

BY MR. SLATER:

Q. And the conclusion was there is a risk -- over 96 nanograms, you can't sell it anymore; right?

MR. INSOGNA: Object to form.

A. That's not their conclusion in this paper, no.

BY MR. SLATER:

Q. No, I'm not saying Gomm. I'm talking about the FDA.

MR. INSOGNA: Dr. Catenacci is not offering regulatory opinions.

MR. SLATER: I'm just -- well, let me ask -- all right. Here's the question.

BY MR. SLATER:

Q. The FDA determined that there was too much risk to sell these pills over 96 nanograms of NDMA; right?

That was the level they eventually set; right?

MR. INSOGNA: Same objection.

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A. According to their statements online that we talked about before, they made an assessment to take these off the market and to evaluate whether or not there was a risk based on some evidence, but in the meantime when it was safe to do so, when there were replacement medications that did not have the impurities, to then go do that, but I think as we mentioned before, even with such potential risks that it was still deemed to be a lower risk than stopping the medications themselves.

BY MR. SLATER:

Q. While getting onto a new medication over the next several days or weeks; correct?

A. Or months, or whatever it was. Right.

Q. Let's go to Page 359, the very bottom, please. At the very bottom of the right-hand column they're talking about some limitations of the study, and they say at the bottom of the page, "A further limitation is that due to the limited follow-up time, we were not able to monitor the long-term effects of NDMA-contaminated valsartan for more than three years."

Correct?

A. Yes.

Q. And you would agree this is a short-term

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study and they were not able to evaluate long-term effects; right?

MR. INSOGNA: Object to form.

A. This is similar to the question about the same limitation in the other study, the Pottegard study, that we talked about before, and that with the current data that we have and the evidence that we have, they were assessing a question that can be assessed, which is this is how long we've got follow-up based -- since -- on the time frame that we're dealing with here.

So their analysis, which is appropriate, and their acknowledged limitation is that it's looking at this much follow-up time. So that doesn't imply, though, that by default it's true that longer-term it's going to show that. This is always -- all they're concluding here is that there's no association during the follow-up time that we've done.

BY MR. SLATER:

Q. Is the answer to my question yes, I'm correct?

MR. INSOGNA: Object to form.

BY MR. SLATER:

Q. They couldn't study long-term effects

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because it was a short-term study?

A. That is what the statement implies and that's -- I would agree that's clearly the case.

Q. Just above what I had read on Page 359, about six or eight lines above that, they state, "Although detailed batch-wise information on potentially NDMA-contaminated valsartan was provided, we had no information on the exact NDMA content of individual valsartan tablets."

Do you see what I just read?

A. Yes.

Q. And that lack of knowledge about the actual exposure levels was a limitation, according to the authors; right?

A. This, again, is a similar limitation across the two epi studies in that we don't know that precisely and that patients may be -- may or may not be getting the medications, but this is what reflects the reality of what was happening, that they may have been getting it for one prescription and then not the next -- in the drugs themselves -- we don't know the exact values, that is random and intermittent and certainly not going to be at the highest level the whole time.

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And this of course is a limitation that we don't know precisely what's in every pill, but we're looking at patients who had suspected lots that had the impurities, and they're accounting for that, so this is what's reflecting the reality of the question of these potential exposures.

Q. And the -- rephrase. And they're also commenting on the reality of the quality of the data they had to rely on and they're acknowledging, as you have, that there are gaps in the data about whether or to what extent people on both sides of the study did actually consume contaminated pills; correct?

MR. INSOGNA: Object to form.

A. Yeah, I think that when they talk about the limitations they appropriately in a study such as this indicate that, despite doing as many adjustments and considering as many factors, that there may still be residual confounding.

BY MR. SLATER:

Q. There's no randomization in this study, or in Pottegard for that matter; right?

A. No, there is not.

Q. And that's an issue with any study of an insurance database; correct? You just -- people are

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self-selected before the study is actually done, so you can't randomize; correct?

A. That's a limitation of any study that's not a randomized study, whether it be a cohort study or case control, or --

Q. Looking now at Page 359 in the top left. The Gomm authors actually comment on the Pottegard study; correct?

A. They do.

Q. One thing that is stated is that the Danish registry study by Pottegard, et al, has only a small sample size comprising 5,150 persons with prescription of valsartan.

And you would agree that that's a weakness of the Pottegard study, that small number of people; right?

A. That is a relative weakness compared to Gomm, that it's smaller.

Q. Going down a little bit further in that paragraph, the authors state, "However, the number of cancer cases in the Danish study was limited, 302 cancers overall, only eight cases each of kidney and bladder cancer. The statistical power for detection of small effects is therefore limited and no precise

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statements on small effect sizes can be made."
You would agree with that statement as well; correct?
A. I do.
Q. And if we flip back to Page 357, please. In the right-hand column, the second paragraph, about six or seven lines down, there's a sentence that says, "However, the sample size of the Danish study was limited to a total of 5,150 patients, which may explain the nonsignificance of the results."
You would agree with that statement as well; correct?
MR. INSOGNA: Object to form.
A. That is a hypothesis to explain why the study was negative.
BY MR. SLATER:
Q. It's a reasonable hypothesis; right?
A. It's a hypothesis that could be tested.
Q. In this study, do you have an understanding as to how they established whether or not someone took contaminated valsartan or not?
A. In the Gomm study?
Q. Correct.
A. Let me look to the methods here to ensure.

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Under the electronic methods, under exposure.
Q. So you're on the page with the little Roman Numeral 2 in the bottom left?
A. Yes, we can start there. So the details here are telling us how they accounted for -- first of all, they had -- all patients included in the study had a prescription for valsartan, and then they explain how they determined who was exposed to potential impurity and who wasn't.
They talk about how they determine the levels when they look at -- within the exposed gift, how many were getting higher doses based on the pharmaceutical registration numbers of any product that had recall for valsartan during that time period.
And they then looked at the amount of the potential or possibly contaminated versus probably contaminated by these records to be able to stratify within those that were exposed and to the dose levels, to look at that, whether or not there was a dose response relationship.
They took into account another -- a number of other factors like long-term users versus those that weren't, and the definition of that is in here based on how many of the quarters during the study period the

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patients were filling prescriptions during that period, et cetera.
So it's all very clearly laid out here how they looked at the data, how they determined who was and who wasn't, when they were, and to look at this as best as possible with the limitations that we mentioned that some of the information just wasn't available. They looked at as many of the parameters as possible to limit the bias as much as possible.
Q. Coming back to my question, I'm really just trying to focus on how they determined whether or not pills were contaminated or not, and looking at where you are reading from on -- or what you're looking at on Roman Numeral 2 page -- there's a sentence that says the marketing authorization holders -- let me start over.
Coming back to my question about how the authors determined whether pills were contaminated or not, they state here on Roman Numeral 2 under exposure, "The marketing authorization holders provided batch-related data on all valsartan drug products for the years 2012 to 2017. This included detailed information on which batches were manufactured using the active ingredient valsartan supplied by ZHP and how

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many packages of these drug products were sold. Based on this information, we calculated the proportion of all packages of valsartan drug products sold made up by packages manufactured using contaminated ingredients."
Do you see what I just read?
A. Yes.
Q. So tell me if I'm right. Similar to Pottegard, the Gomm authors established contamination based on whether the API was manufactured by ZHP and that's how they established contamination; correct?
MR. INSOGNA: Object to form.
A. I think in this one what is a little different, you -- taking on right from that sentence you left off on, it says, "We calculated this ratio for all pharmaceutical registration numbers affected by the recall of valsartan drug products." That's the exact next sentence right after you stopped.
And the other thing I read into it in the actual methods section where they're talking more superficially about what they did, but they said, example, ZHP products. So in other words, it's not limited to ZHP products, but it's any recalled valsartan drug product, according to how this reads.
And so as opposed to the Pottegard study

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where I think we had already discussed and you mentioned we talked about how there were the three groups, whether they were exposed to ZHP or not, this one, which was conducted later and published later where it was done after the fact where more of the recalled products were known at the time, they, according to this statement, used any pharmaceutical registration number affected by the recalls of valsartan drug products.

So I read into that because they had more information, they accounted for all of those -- all of the products that were known at the time that had been recalled.

BY MR. SLATER:

Q. Actually, what they do is what I just read. They say they based it on did the pill come with ZHP API, and then in another place they say, for example, ZHP.

They say basically two different things; right?

MR. INSOGNA: Object to form.

A. They say, example, in the area I mentioned to -- and where you read you say that this is one of -- this is what they're using, is ZHP, but then the

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following sentence they said any recalled valsartan drug product.

BY MR. SLATER:

Q. And they say they calculated this ratio.

Do you have an understanding of what ratio they're referring to?

A. For all pharmaceutical registration numbers affected by the recalls. So --

Q. So they're looking at the -- well, you answer.

MR. INSOGNA: I'm sorry. What's the question that's pending?

BY MR. SLATER:

Q. Where they refer to the -- we calculated this ratio. What ratio are they talking about?

A. The proportion of all packages of valsartan drug products sold made up of packages manufactured using contaminated ingredients. The sentence just before that.

Q. And we have this what I'm terming a conflict where their definition of contaminated -- in one place it says ZHP in another place it says, for example, ZHP.

It's not really clear which one it is;

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right?

A. I read it as being that they are using anything at the time of this study that had been recalled.

Q. If they limited it to -- well, rephrase. I'll withdraw that.

There's a risk of residual confounding in this study; correct?

A. I think that we mentioned that earlier, yes. There's always risk of residual confounding in studies like this, even with the best efforts to account for confounding variables.

Q. For example, there's no information about who in the study had potential influencing factors, such as smoking, nutritional habits, genetics?

Those factors were not integrated into the analysis; correct?

A. That's right.

Q. That would be a weakness of the study; correct?

MR. INSOGNA: Object --

BY MR. SLATER.

Q. It's inherent to the data, but it's a weakness; correct?

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A. It's a weakness to the data in that it doesn't account for known risk factors for cancer. I think that ultimately usually those types of confounders would -- not accounting for them could lead to false positive signals in the study.

Q. Look, please, at Table 1.

A. Table 1. Okay.

Q. On my reading of this table, it appeared that the unexposed group or the presumed unexposed group was generally healthier than the, quote/unquote, "exposed group." I saw less diabetes, less heart failure, less polypharmacy.

Would you agree with that assessment of the two groups?

A. I noticed the same, that most of these risk factors had a higher percentage of patients that were in the exposed group, yes. I would also point out things like spironolactone, which is a drug that's often given in the setting of cirrhosis of the liver, since that I think is pertinent and relevant to this particular paper that I'm sure we'll get to.

And also just the bigger one at the bottom, the Charleston comorbidity index, which sort of summarizes all of those things, all comorbidities -- is

higher in the one -- the patients who have higher comorbidity indexes, there's a higher percentage of them in the exposed group. So that's an important factor for sure, yes.

Q. And those factors can be strong confounders that traditional statistical techniques cannot always control; correct?

A. Potentially, yeah. And especially when you try to -- that doesn't necessarily mean you've been able to eliminate all of the confounding.

Q. For example, a traditional statistical technique that doesn't control for those factors would be the Cox model that was used here; correct?

A. No, I think very clearly they state here that they did adjustments based on these confounding variables, including all the ones we just mentioned. And that said, there's still going to be potential for residual confounding because these patients clearly, as you've pointed out, have higher risk factors at baseline for getting cancer, and so despite trying to make that adjustment -- that's why all of these hazard ratios are called adjusted hazard ratios -- and they go through that in the methods pretty detailed -- and they even adjusted by just a few of them versus all of them

to see if there are any major differences, and ultimately there weren't any major differences.

But I think that we're agreeing that, despite making all of those adjustments, there could still be residual confounding that, as I mentioned, usually would lead to a signal that's a false positive signal if you don't account for an underlying factor that was there.

Q. Let's look for a moment at your report if we could. I'm looking at Page 39. And I think, for the record, I just got a note from Chris that we marked the Gomm study as Exhibit 14, just for the record.

If you could look at your report, Page 39. You make a statement in the middle of the page, or a little below the middle of the page. You say, "In other words, taking NDMA containing the valsartan impurity was not associated with any increased risk in overall cancer or with any specific cancer."

Do you see that?

A. Yes.

Q. Looking now at Page 359 of the study, the Gomm study, on the left-hand column. They state in the second full paragraph, "For liver cancer, however, we observed a statistically significant association."

Correct?

A. I missed where you said we were, but I do remember it saying that, yes.

Q. I'm on Page 359, left-hand column, second paragraph.

A. Okay, yeah. Uh-huh.

Q. Liver cancer is a specific cancer; right?

A. Yes, it is.

Q. So when you said that NDMA containing the valsartan impurity was not associated with any increased risk in overall cancer or with any specific cancer, that's an incorrect statement; correct?

A. When it says any specific cancer, that is inaccurate with respect to the liver finding here.

Q. The authors continue where I was reading. "This is interesting, as from a biological perspective liver cancer is the most likely form of cancer to resulting from NDMA contamination."

That's, I guess, their viewpoint; correct?

A. Yes. Yes.

Q. Do you agree with that viewpoint?

A. I think that it's an interesting finding, given that that is -- one of the risk factors is that that's where the NDMA is metabolized, in the liver, and

that at least in the Keto (ph) studies at very high doses, that's -- they do -- they have been noted to have liver cancers, and that the finding here -- one of many findings that's being looked at -- suggests that, at least at a very, very small effect size.

I think that's an interesting signal that comes out of this paper, that as we both mentioned has confounding, could be a positive -- a false positive signal based on not adjusting for a lot of different things that we just talked about.

As we talked about earlier, it's an interesting finding. Is it enough to hang your hat on and call definitive, as opposed to this should be assessed in an independent cohort that is looking specifically at this question, as opposed to one of many things? That's how I would frame the finding, but it is in that context something that I would say.

The only other thing I would point out is that in other animal models, I think I mentioned earlier, is that the nonhuman primates at very high doses of some of these agents don't show liver cancer and that in the Gomm study, even as we both agreed that there is a hypothetical potential of confounding of some of the non-ZHP agents in the control arm, there

are zero liver cancer patients.

So there are two human epi studies that show different things with respect to, say, even just liver, and so this is why this is not consistent across all the data, even in the human epi data. And so like I said in summary, it's interesting. It's something that should be followed up and looked at independently, but it's not enough to say, okay, this is enough to move forward and reject the null hypothesis and go to the alternative hypothesis for that specific cancer.

Q. Could you go to Page 358, please? In the right-hand column, the first full paragraph, along the same lines as what we just talked about, they state, "The analysis of individual cancer types showed a significant association between potentially NDMA-contaminated valsartan and liver cancer, adjusted hazard ratio 1.16."

Then they give the confidence interval, 1.03 and 1.31, and a P of zero point -- of .017; correct?

A. Yes.

Q. Is there significance to a P value in one of these analyses?

A. Yes. If you look at their statistical

methods, the last sentence of their electronic method, it says that all analyses were performed and considered statistically significant for a P value of less than 0.05, which is what we talked about earlier.

And so in other words, they're admitting they didn't correct for multiple testing in this study, and so as we explained earlier, that this is at risk of a false recovery rate, there's a false positive rate, by looking at multiple things slicing and dicing the data multiple different ways, which was appropriate to see if there's a signal somewhere.

And essentially, of all the things assessed in just this study, let alone including all the things looked at at Gomm, let alone if we're looking at the full body of evidence of all the data we're looking at here, one signal comes out. You just have to be very cautious and skeptical that that's real, especially when the effect size is like so small.

So ultimately I think I've summarized and said it many times, is that this has to be followed up on and this alone is not enough to just say, okay, I'm going to reject the null hypothesis, that there's no association with liver cancer, and that I'm going to accept that it's truly there, based on this one finding

based on the whole body of the other information that we've been evaluating here. That's just how science works.

Q. What's a P value?

A. The P value, as we talked about earlier, is the value with which you set somewhat arbitrarily, but has been a convention for decades, at .05, meaning that you're willing to accept that what your association is in any given study or whatever analysis you're performing -- is that less than five percent means that you have a less than five percent false positive rate of the finding that you're seeing. And so the problem with that --

Q. Doctor, I only asked you what it means. I didn't -- I just wanted to ask -- I'm just asking for terminology.

MR. INSOGNA: Adam, don't cut off the --

MR. SLATER: Yeah. I'm sorry. I don't mean to interrupt, but we're trying to use time here, so I just wanted to kind of get us on track with that. That's all I'm trying to say.

MR. INSOGNA: Had you finished your answer?

A. I was just going to say -- I had already

said it before -- that if you look at multiple things then, then you have to take that into account because then your false positive rate goes up. And you -- by chance, you could find something by -- that you're calling statistically significant because it's less than .05, but you've looked at multiple different things, which increases your risk of a false positive rate. That's all.

BY MR. SLATER:

Q. A P value of .017 means that there's less than a two percent chance that that finding is due to chance; correct?

That's what that means statistically; correct?

A. As a standalone assessment of just looking at that question, yes. But not in the context of looking at multiple different things.

Q. You disregarded the increased risk for colorectal cancer and uterine cancer in Pottegard because they didn't reach statistical significance in that study; correct?

MR. INSOGNA: Object to form.

A. I criticize -- I didn't criticize them. You were asking --

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BY MR. SLATER:
Q. I said rejected.
A. I was trying to explain to you why as a scientist we wouldn't look at that with -- we would look at that with skepticism that that's a real finding, the point estimate, given that there's wide confidence intervals and that it's not even closely statistically significant and the numbers -- are so small. That's a different question altogether.
Q. My only question is this. The findings of increased risk for colorectal cancer and uterine cancer in Pottegard did not reach statistical significance, and you stated in your report that you don't credit those findings as a result of the failure to reach statistical significance.
I understand that correctly; right?
MR. INSOGNA: Object to form.
A. In the same way that I rejected that some of those look like taking the drug is protective, because it goes the other way. That's the risk of looking at subgroups, is that you get random variations.
BY MR. SLATER:
Q. Is the answer to my question yes?

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MR. INSOGNA: Object to form.
A. Can you repeat the actual question?
BY MR. SLATER:
Q. The data showing increased risk for colorectal cancer and uterine cancer in Pottegard, you in your report made it clear that you did not credit that study as establishing any risk for those cancers because they did not reach statistical significance; correct?
A. Not exactly, no. Because even if it did, if it was a multiple assessment and one out of many looked like it as a subgroup, we would not look at that with definitive conclusion. That's my point.
If it was the main analysis which was powered for that to limit false positive and false negative rates, then that's different. But if it's a subgroup and you're looking at multiple different subgroups, then that's not the only reason why I rejected it. It was clearly not significant. But it's also because it was just a small subgroup analysis.
Q. You said you wouldn't draw any definitive conclusions based on that. Is it fair to say you wouldn't draw any definitive conclusions one way or the other based on Gomm and Pottegard, recognizing all the

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limitations we've discussed the last two days?
MR. INSOGNA: Object to form.
A. No, that's not true. I mean, that's --
BY MR. SLATER:
Q. That's all I asked. It's a yes or no.
A. No. No. It's clearly negative for the prior endpoint, both of them, for any cancer being at higher risk. That's the clear answer that's not true --
Q. So now coming back -- all right. New question.
So in Pottegard, colorectal cancer, uterine cancer, increased risks are shown but not reaching statistical significance, and that's one of the reasons why you say, "I don't think there's an increased risk"?
In Gomm, according to the authors in a peer-reviewed article that you're saying is one of the two most important articles you've reviewed, they do find an increased risk for liver cancer reaching statistical significance, and your response is, "Well, in that case it might be due to chance."
Do I understand you correctly?
MR. INSOGNA: Object to form.

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A. Yes, that would be the scientists' impression of that data, is to say we have to be cautious with that finding and not conclude that it's true.
BY MR. SLATER:
Q. We also need to as a scientist say that could also be very meaningful and could be an important signal that this contamination did cause cancer to people?
That's also something you have to take into account if you're using an objectively reasonable methodology; right?
MR. INSOGNA: Object to form.
A. Yes, I've acknowledged that, that that is something that you would not ignore, and that you would have to follow up on in independent studies and see if you're seeing a consistent outcome, which many times the problem is -- and which sort of emphasizes what I'm trying to say -- is that it doesn't.
And so as an example, we have another study that was done that showed no liver cancers in either group that we're talking about that maybe have some contamination of the -- into the control arm with some of these agents, and there's still no liver

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cancers. So now we have discrepant data not even consistent from these two studies.
BY MR. SLATER:
Q. The two studies that you're relying on as over and above all the other evidence in the case have conflicting results; right?
MR. INSOGNA: Object to form.
A. They have results that are very consistent with random variation when you keep looking at data multiple times, yes.
BY MR. SLATER:
Q. If we could put that aside for now. Bear with me for a second. I'm trying to tidy up over here for a moment.
You mentioned something yesterday that I want to come back to. You said -- well, rephrase.
Yesterday I asked you about whether or not it would be ethical to study in a randomized double blind study, the gold standard-type study, study people getting the valsartan that was contaminated at the levels we've seen and have another group of people that gets confirmed uncontaminated valsartan and to run a study.
Remember we talked about that yesterday?

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A. Yes.
Q. And I asked you about running such a study to evaluate the risk of cancer in humans from exposure to that NDMA, and we talked about that; correct?
A. Yes.
Q. And you said you thought there was a study you had seen where that was actually done I think with Zantac or something similar was done with Zantac.
Remember you said that yesterday?
A. Yeah, I said that in response to -- your question is, would it be ethical to give a product that was thought to be having an issue such as this to patients prospectively and randomize them? And that was an example of a study that did just that.
Q. The JAMA article you're talking about is Florian (ph); right? Or do you not know the author's name?
A. It sounds familiar. It was in June of 2021.
Q. 18 participants who were given Zantac a handful of times over the course of about a month.
Does that ring a bell?
A. That's right.
Q. And that the people who ran the study

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confirmed with regard to every single pill that the NDMA was well below the acceptable daily limit set by the FDA.
Do you recall seeing that in that study?
A. I do.
Q. And they actually stated levels of 6.3 nanograms, 7.5 nanograms, and 10.5 nanograms.
Do you remember seeing that?
A. I do.
Q. And all they were studying in that study was whether or not taking those pills would increase the level of urinary excretion of NDMA; right? That was the endpoint; correct?
A. The endpoint was to evaluate whether changes in the NDMA levels in the urine, yes.
Q. So coming back to my question, can you imagine any IRB in the United States approving a study where the valsartan pills sold in the United States by Teva that are confirmed to be contaminated at the levels we've seen of NDMA and NDEA would be given to study participants on one side of the study and other people would get valsartan that they know is not contaminated, follow the people for some number of years while they take it, then follow them out for 30

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years to see how many people get cancer?
Can you imagine that any IRB in the country would find that to be an ethical study?
MR. INSOGNA: Object to form.
A. And let me come back, because it's important to answer your question, because you haven't looked at the whole part of that study -- the other study they were talking about with ranitidine or Zantac. And that is that in that storyline, one of the issues is that the ranitidine gets degraded endogenously after being eaten and may be affected by different foods, et cetera, and that study took that into account and was looking at where the levels actually are far higher -- that's the hypothesis -- compared to the exogenous, which is very relevant here actually, too, with nitrosamines.
And so it's not only the exogenous amount that they're talking about in NDMA -- of NDMA in the Zantac, but it's also all of the complication that happens upon degradation, which is one of the issues at hand with Zantac. And that study was doing just that and randomizing the different diets even to evaluate if different diet could affect that.
And all of those hypotheses were being

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tested there in a setting where it possibly could cause cancer, and they did it prospectively in a randomized fashion and it was not deemed unethical. And so the same question now that you're asking me, I can say is that if it was asking a question prospectively and it was -- and analyzing such as question as this to see if something that we don't know for sure is -- we don't have evidence here that says that this at these levels are clearly associated with cancer and someone was doing a prospective study that was well-designed, then I think it would be difficult to do in this setting, but it has been done in an analogous situation already.

I don't know what would happen in another proposed study and whether an IRB would accept it or not, but you asked me if it could be and I'm giving you an example where that exact thing was done in an analogous storyline. That's all.

BY MR. SLATER:

Q. So you have no opinion on my situation about whether that could be done; correct?

MR. INSOGNA: Object to form.

A. I don't know, which I think was my answer yesterday, too.

BY MR. SLATER:

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Q. By the way, one question just to close the loop on Zantac. It's been proven that it actually doesn't increase the levels of NDMA in the body; right?

It -- the Zantac itself doesn't get somehow activated to create more NDMA? That was a hypothesis that it doesn't appear to have been proven; right?

A. The hypothesis was whether or not taking the ranitidine would increase urine excretion or not depending on diet changes, and they did --

Q. And they didn't; right?

A. And they didn't see any changes in the urinary excretion.

Q. Now, if I can find my notes, we'll turn to the Hidajat study for a few moments. That's apparently a big if.

MR. SLATER: And Chris, I'm going to assume you're going to mark this as Exhibit 15. Correct me if I'm wrong.

[Exhibit 15 marked for identification.]

BY MR. SLATER:

Q. Now, looking at your report also concurrent with looking at the Hidajat study -- because you talk about it on Page 43 of your report; correct?

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A. Yes.

Q. If you took a scale and you said, all right, I have to put evidence that I'm looking at on one side or the other pro or con to whether or not NDMA can increase the risk for cancer in humans on one side and saying on one side yes and on the other side no, the Hidajat study would go on the yes side; right?

A. As a simple answer, I would say there are so many problems with this paper in terms of putting it on the yes side that although on the surface say the conclusion is that there's an association, when you look at the numerous problems with saying that with respect to the question we're asking today, it would be a soft yes.

It would -- when you're weighing the data and looking at all of the evidence, that would not play a large role into saying -- for the question I've been asked -- in terms of the impurities found in valsartan at the trace levels that they've been found, if they increase the cancer. In that question on the yes/no side, it would be a very -- there's also weight on how much was on each side -- it would be very, very low.

Q. You certainly wouldn't put the Hidajat study in the no side; right?

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A. No. I agree with that.

Q. You talked about the limitations and confounders.

You talk about that on Page 43; right?

A. Yes.

Q. I'm not asking you to list them, but did you find any strengths of this study -- anything about it that you would say, yes, this was a good part of the study?

MR. INSOGNA: Object to form.

A. The positives I guess would be that they're making an effort to try and evaluate a question.

BY MR. SLATER:

Q. Pull out the Hidajat study for a moment. Page 225 if you -- 255, I should say.

And do you see the column that talks about the exposure levels of NDMA?

A. The column that talks about exposure level --

Q. In the middle?

A. Yes. Okay.

Q. And are the exposure levels listed from lowest to highest?

A. Yes.
Q. Is each exposure above the baseline associated with a statistically significant increase in the rate of cancer?
MR. INSOGNA: Object to form.
A. The way you asked that question, they all have less than -- less than P values that would call them statistically significant, yes.
BY MR. SLATER:
Q. Am I also correct that the higher the exposure, the higher the cancer risk, according to this table?
A. Yes.
Q. So does that mean there was a statistically significant dose response relationship?
A. In that focused question, without taking all the confounding into account, yes.
Q. When NDMA is inhaled, is it metabolized?
MR. INSOGNA: Object to form.
BY MR. SLATER:
Q. In the human body?
A. I think studies that demonstrate or evaluate the pharmacokinetics of this agent that don't take it orally, which as I think we talked about

earlier where it's absorbed, it goes through the portal system, it goes to the liver.
In analyses that looked at what happens if it goes through a different route, in fact it gets metabolized mostly in the liver also despite that, because eventually it gets there, and most of it gets eva -- gets metabolized -- and that's where the enzyme, the P450 enzyme, exists at that concentration that do that, but the answer is yes, eventually that would do that.
Q. So inhaled NDMA would be metabolized in the liver; correct?
A. Eventually.
Q. You mentioned in your analysis of the study that there was a lack of individual smoking data, and I think you said that the authors made no effort to control for smoking history.
Do I understand that correctly?
A. Where do you say that, just so I can read it?
Q. It's on Page 43 in the second paragraph, about five lines up, where you say, "Finally the Hidajat study made no effort to control for smoking history."

A. Yeah. Yes.
Q. Did they perform a Monte Carlo analysis?
A. I don't know. I'd have to look.
Q. Do you know what a Monte Carlo is?
A. I do not.
Q. Go to Page 257, please.
A. Okay.
Q. If you look at Page 257, the left column, the second-to-last paragraph. It's a long paragraph, and what they say about halfway down that paragraph, they state, "To obtain some indication of the possible confounding effect of smoking in this cohort, we used a statistical external adjustment method."
Do you see that?
A. I do.
Q. They say, "External Monte Carlo analyses based on information on smoking prevalence, ex-smokers, and never-smokers from a cohort of rubber industry entrants after 1982 indicated that mean bias is only 1.6 percent compared with the general population." And they go on and then they conclude suggesting that confounding by smoking in this cohort was likely not a significant confounding factor.
Do you see that?

A. Yes, I recall reading this. Yes.
Q. So they did attempt to control for smoking; correct?
A. Well, I guess the way I was reading that is that they didn't have smoking exposure from these people in this cohort, so what they did was they tried to extrapolate from other data to see how that might play a role, but I think we've established through all of the studies, whether you like them or not, whether they're positive or negative, particularly a study like this with so many confounding variables, that it's nearly impossible to adjust for all of them. They can make an effort, but I think we would have to agree that this is trying to mitigate a huge problem in the analysis.
Q. You stated that the Hidajat study made no effort to control for smoking history. That's what you stated in your report.
That's an inaccurate statement; correct?
A. They weren't able to get smoking histories of the patients that they were analyzing, is what I was meaning by that statement. They didn't have it, so they couldn't adjust for it, and they had no -- they didn't make an effort to get smoking history from those

patients.
Q. Your report says that the study made no effort to control for smoking history. Just looking at those words, you would agree with me that they did attempt to control for smoking; correct?
A. They did this analysis from patients that -- from other patients that weren't these actual patients, making a huge assumption.
Q. Well --
A. But they didn't account for their own patients. They didn't --
Q. You don't know -- just to be clear, you said you're not sure what a Monte Carlo analysis is; right?
A. I don't know the details of the statistical measures, but I -- which is what you were asking me, and I don't -- but assuming they did that properly, this is an assumption from people that aren't even the people they're talking about in this study.
Q. It's a statistical tool that was used in a peer-reviewed article and you didn't mention it at all in your report?
Is that a true statement?
A. I didn't mention this part of the

analysis, no.
Q. All you said in your report is they made no effort to control for smoking history. In order to be balanced, wouldn't it have made sense to say they did a Monte Carlo analysis and state what they found so at least you could show both sides and show that they did make an effort to address smoking and didn't just ignore it?
MR. INSOGNA: Objection. Form.
MR. KUM: Objection. Form.
MR. INSOGNA: Compound. Argumentative.
A. I didn't mention every point on every article about every thing. My summaries here of this paper are pointing out the many, many limitations of this study, which was used heavily by plaintiff experts to look at a question that is far removed from what this study is looking at.
So I didn't put that there. I could have -- I -- we could go through this paper and I could have missed some of the things that would negate this even further. I was just pointing out a few examples of how this is severely confounded and has so many significant problems with the question at hand here.
BY MR. SLATER:

Q. Coming back to my question, if one were to come to your report not having the same background we all have, not being so familiar with all this material, and just read that sentence, finally, the Hidajat study made no effort to control for smoking history, that would be misleading in the sense that it would suggest they ignored the issue when in fact we know they actually did a statistical analysis to address it and drew a conclusion on that; correct?
MR. INSOGNA: Object to form.
A. I answered already that I didn't put every point on either side in here. I was pointing out a major problem that they don't have the patients' smoking history in this analysis.
BY MR. SLATER:
Q. Is my statement a true statement?
MR. INSOGNA: Object to form.
A. No.
BY MR. SLATER:
Q. In order to give a more fair and balanced -- well, rephrase.
In order to give a balanced view of the issue of smoking, it would have been appropriate to state in your report what the authors did with regard

to smoking; correct?
MR. INSOGNA: Object to form.
A. I was pointing out highlights of this paper in terms of significant limitations.
BY MR. SLATER:
Q. In your report on Page 43, in the middle of that second paragraph -- bear with me for one second. Ah.
On Page 43 of your report, in the second paragraph, about two-thirds of the way down, you say, "Moreover, the Hidajat study used estimations of NDMA exposure based on job title and air quality measurements associated with those job titles, while also assuming study participants remained in the same position throughout their careers. That is a significant and in my view implausible assumption and makes the estimations inherently questionable."
That's what you stated in your report; right?
A. Yes, I see that.
Q. Now, look at Hidajat, if you could, Page 251, top right-hand corner of the page under the heading exposure assessment. Halfway down that paragraph it says, "Because only job information in

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1967 was available, the primary analyses assumed all subjects remained in the same factory department -- i.e., not necessarily in the same job -- throughout their careers and were employed until retirement at age 70, death, or emigration."

Do you see that?

A. Yes.

Q. So when you said in your report that Hidajat assumed everybody stayed in the same position, that was incorrect because they explicitly said they did not assume people stayed in the same job; right?

A. They stayed in the same department, same position in the department.

Q. You said that they will -- you said in your report -- you referred specifically to job titles, and then you said while also assuming study participants remained in the same position.

You were referring when you said same position to the same job? That's what you meant; right?

A. In the same department, as it states here.

Q. But that's not what your report says, because you didn't say that?

A. Where --

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Q. I mean, let's look at your report. You say, "Moreover, the Hidajat study used estimations of NDMA exposure based on job title and air quality measurements associated with those job titles while also assuming study participants remained in the same position throughout their careers."

You're obviously when you say same position talking about the job title; right?

MR. INSOGNA: Object to form.

A. And the job titles would be grouped by department; okay? So I'm not being as specific as you would like, and I think that clearly it states here that they stayed in the same department, which is what the meaning of this was, to clarify.

BY MR. SLATER:

Q. Well, you said that is a significant and in my view implausible assumption and makes the estimations inherently questionable, the suggestion that someone would stay in the same job for all those years.

But it's certainly not implausible that someone would stay in the same department, is it?

MR. INSOGNA: Object to form.

A. It's an assumption, and people move around

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to different departments, and to assume that they wouldn't is a huge assumption; that's all.

In fact, let me just characterize -- of all the limitations in this study, I think that that's the least important, actually. Of all of the limitations, which include all of the exposures to all of these other known carcinogens, Type 1 carcinogens in many cases, that are inhaled, not even orally ingested here, that are -- this is the bigger issue with this paper in terms of confounders, to ask the question about -- we're not even -- we're talking about NDMA at trace levels in a pill that's taken for a few years, as opposed to over decades exposure here to so many different carcinogens.

It's really -- I mean, it's an extension, it's a surrogate of surrogate of surrogates, trying to look at a question, and of all the evidence we've talked about so far, this is the least evidence -- the least weight evidence that I would put on this one.

BY MR. SLATER:

Q. Just to be clear, you're not claiming to be an expert on whether people would stay in the same department in the rubber industry in the United Kingdom?

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You don't have any knowledge or expertise in that field at all, would you?

A. Nor would I say that they most definitely all stayed in the same department. I mean, it's my assumption. That is -- I think we're both agreeing on.

Q. My question is this. You're not stating that you have some expertise or any special knowledge about whether people would stay in the same position or not or the same department or not; right?

A. I don't have special expertise other than just common sense, that that's just an assumption that that not necessarily is true.

Q. Do you know what the departments were in the United Kingdom in the rubber industry during the time this study was being conducted?

Do you know what the departments were called?

A. No.

Q. Do you know how many departments there were?

A. No.

Q. Do you know if there may be two departments in the whole factory?

A. No, although that's not what it sounds

like here as they're calling it more of a -- multiple different potential departments.

Q. You have absolutely no idea how many departments there would have been in any of these factories; right?

A. No.

MR. INSOGNA: Object to form.

A. Nor does it matter in the grander context, as I've already mentioned.

BY MR. SLATER:

Q. Do you know if people in that industry in that time period saw these jobs as jobs for life and would settle into a department and make that their job for life and would work until they either died or stopped working?

Do you know if that's how it worked back then?

MR. INSOGNA: Object to form.

A. I don't know. It's possible.

BY MR. SLATER:

Q. You have no idea; right?

MR. INSOGNA: (Inaudible) possible.

BY MR. SLATER:

Q. You have no idea; right?

A. Not relevant and not --

MR. INSOGNA: Object --

A. And potentially possible.

BY MR. SLATER:

Q. In your report you mentioned on Page 43 the Straif study from 2000; right?

A. Yes.

Q. That study also found statistically significant increased risks for multiple cancers; correct?

A. Yes, with the exact similar confounding problem and limitations as Hidajat. Also that --

Q. Do you think that it's difficult to study the risk to humans from exposure to NDMA because of the limitations on how you can set up studies for whether or not you can give NDMA to humans, for example, as we've talked about, and because of just how the world works?

Is it just hard to set up a study that you would say, "That's a great study. That can answer the question"?

MR. INSOGNA: Object to form.

A. It relates to the question about prospective randomized study, which of course would be

more of a gold standard to ask a question and minimize as many biases as possible. I already mentioned that there have been similar studies in analogous cases, but I will agree that it's difficult to do randomized studies for various reasons and one of them is it's challenging to do and to coordinate.

But that doesn't mean that we should then rely solely on evidence that's not good and just say, well, we're going to do that instead and just agree and believe it. We have to look at it skeptically; that's all.

BY MR. SLATER:

Q. Do you know what the tobacco industry and their experts were saying early on about the quality of the studies that people were saying proved that tobacco caused cancer?

Do you know what they were saying at that time?

MR. INSOGNA: Object to form.

A. I don't know --

BY MR. SLATER:

Q. Would it surprise you to find out that basically were saying the -- they were saying the same thing -- let me rephrase.

Would it surprise you to learn that the tobacco industry was basically making the same arguments that we're hearing from you and the manufacturers of the contaminated valsartan back then?

MR. INSOGNA: Objection.

MR. KUM: Objection. That assumes facts not in evidence.

MR. INSOGNA: Same objection.

MR. SLATER: Wait. I'm sorry. Let me just -- before you answer, Doctor. Did somebody just object and say that it assumes facts not in evidence? This is a deposition. We're not putting anything into evidence till we get to trial, counsel.

Am I missing something, or do -- would you like to maintain that objection?

MR. KUM: Well you're making an assertion without laying a foundation for it, so --

MR. SLATER: Okay. Assumes facts not in evidence. Okay.

BY MR. SLATER:

Q. Doctor, you can answer the question.

A. Can you repeat it for me, please?

Q. Sure. Would it surprise you to learn that the tobacco industry made very similar arguments to

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what we're hearing here in defense of these valsartan cases with regard to the risks of cancer from smoking?

MR. INSOGNA: Same objections.

BY MR. SLATER:

Q. Same type of thing? We don't have RCTs. We have to -- you can't rely on animal models. Short-term studies. We're not seeing a lot of effects on these short-term studies of people who smoked.

Would it surprise you to hear that all the same arguments were basically being made to defend the tobacco industry?

A. My response to that is, is that science always will tell the truth if it's done properly, and what you're calling tobacco -- that's a Type 1 carcinogen, and we know that, and there's evidence to support that, and the data was done to do that.

We're asking here now, do we have enough evidence to say that? And I'm telling you the answer is no, there's not enough evidence to say that. That's all I'm saying.

Q. Do you know that the experts for the tobacco industry said exactly the same thing that you're saying here when they were defending tobacco before it was recognized widely around the world to be

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a dangerous carcinogen for humans?

MR. INSOGNA: Object --

A. That's irrelevant. From a scientific perspective of my -- what I'm asked to do, we are asking if we can reject the null hypothesis, which is -- you have to start from that -- there is no association, there is no causation -- and prove it to me that there is with a body of evidence.

So you can't equate that and this which has completely different storylines. There's not enough body of evidence to make that call at this point. Both can be true, in other words.

BY MR. SLATER:

Q. In terms of your methodology, does Hidajat even figure into the analysis, or do you just say this is a study I don't have to really consider because of the issues I've seen, so I don't even take it into consideration?

A. I think I mentioned yesterday that when you're looking at a question like this, you have to consider all available evidence and weigh it. And we have evidence looking at the actual question that was asked of me, which is, do these pills that have trace levels, very small levels of this agent, increase the

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risk of cancer?

And we have some cohorts that actually were looking at exactly that with the exact pills and controlled in some ways -- everyone was taking valsartan, et cetera. We already talked about some of the confounding that's residual in those studies. But those studies are negative.

And now we have a whole body of studies that are based on looking at exposures in the occupational setting to in this case rubber workers that have exposure to so many other carcinogens that it's nearly impossible to account for that are looking at extensions of the question at hand here at doses probably far higher than what we're talking about in these trace levels in the pills.

Then it's not like I'm not looking at it or I'm not considering it, but it's certainly not anywhere near the level of where I'm putting weight on this particular question at hand. It's not enough --

Q. So --

A. -- that these studies are positive to say, okay, so we can move on now and establish that not only is there an association, but now it's causing the cancer.

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Q. Well, I probably can save us a bunch of time right now perhaps with a couple questions based on what you said, because I think I'm getting a good idea of what your understanding is.

There's obviously a lot of dietary studies that you've looked at and analyzed; right?

A. Yes.

Q. You talk about them in your report; right?

A. Yes.

Q. You would agree that there are dietary studies that support the proposition that NDMA increases the risk and actually causes cancer in humans and there are some studies that were not definitive on that question or that you might even say support your opinion; right?

MR. INSOGNA: Object to form.

A. You're using the word risk, but I think I would use associations that have been positive or negative, depending on various studies. And --

BY MR. SLATER:

Q. I'll use your vocabulary. Let me ask again.

You would agree that there are dietary studies that support a significant association and

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there are studies that don't or are not definitive one way or the other; right?

MR. INSOGNA: Object to form.

A. There are studies that have shown positive associations and others that haven't in looking at the same cancer type and looking at other cancer. In fact, most of the studies that expert plaintiffs rely on don't mention anything about diet causing hepatic or liver cancers, which is the whole focus of the human epi data, and we're not talking about it. We're talking about gastric cancer and other colon cancer over here in the diet.

So this is an example of, okay, it's all over the place and there's no consistent story, and so when I'm looking at this to say is there enough evidence to change me from the null hypothesis -- alternative -- about any -- about all cancers, the answer is no. And if I'm looking at a specific cancer, there's no consistent trend throughout any of this either.

And so, yes, the dietary sub -- back to your question -- has some for and some against, but it's very non -- it's inconsistent, and it's not something one could rely on given all the other

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confounding issues with the diet stuff that I've mentioned in my report.

BY MR. SLATER:

Q. If I understand your opinion ultimately -- and please correct me if I'm wrong, even though I know you're shy about saying that --

A. That was sarcastic.

Q. I'll start over. I'll start over.

Tell me if I understand. Based on your review of everything, you looked at everything and you weighed it as you weighed it and you came up with a conclusion. Your conclusion is the evidence is not sufficient to establish that the exposure of individuals to the valsartan with the NDMA and the NDEA levels in the pills that were actually sold in the United States increased or cau -- the risk for cancer -- or caused cancer to humans?

Your position is the evidence is not sufficient to say yes to that, and that's your opinion; right?

A. That's my opinion, yes.

Q. Your opinion is not that the evidence proves that the answer is no? You're not taking the position that, based on the evidence, it's been

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established that NDMA does not increase the risk for cancer or cause cancer in humans; correct?

A. That's not how science works, but certainly any of the data that is reliable or the more reliable data, the answers have been no in those reports. In other words, there was no association in Gomm and all cancers. There's no association in Pottegard and all cancers. But that's not how -- I'm not trying to prove that it doesn't cause based on the scientific approach.

Scientific approach is to start with the hypothesis that there's no difference with this and I need to prove that there is based on some sort of evidence, and there is no such evidence to do so.

Q. I just -- the reason I asked the question is because, as you understand, I have to go through what your opinions are. I didn't see an opinion saying that the evidence proves it doesn't increase the risk or cause cancer.

That's not an opinion you've drawn, it's not what you've done here; right?

A. That's not the opinion I'm stating explicitly.

Q. There's some discussion in your report

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about endogenous formation of NDMA.

You've looked at that and commented on it in your report, that subject; right?

A. Yes.

Q. Again, I'm trying to be good with our time right now, so I'm going to try to cut to the chase with some things.

I did not see -- an opinion as to some level of endogenous formation of NDMA that you have said, "Based on my review of the literature, this is what's being formed in the human body and I ascribe to this model and I think this is the right amount"?

You haven't formed that opinion; correct?

MR. INSOGNA: Object to form.

BY MR. SLATER:

Q. Was that question convoluted?

A. A little bit, but I -- my summary --

Q. Let me just ask it cleaner. I'm sorry. I didn't mean to interrupt. Because counsel objected, and he's probably right on that one. Let me ask it again.

I did not see in your report an opinion as to an assumed rate or quantification of endogenous nitrosamine formation in the human body.

You didn't form an opinion on that question; right?
A. I didn't calculate a rate on my own, no.
Q. You didn't, for example, adopt a specific article and say this is the model I think is the right one, so this is the one I'm going with?
That's not an opinion you have that you've drawn in this case; right?
MR. INSOGNA: Object to form.
A. And to summarize that part of the -- my report and my review of the literature on that is that you're looking at various studies, that there is a known endogenous rate and that the levels, although they range depending on how they're calculated in given authors and different papers, they're high.
They're much higher on orders of magnitude than what we're talking about even just with exogenous diet, and when we're talking about sort of the FDA limit, the ADI, and the amounts that are in these actual pills.
So that's the sort of general understanding from the diet endogenous formation that I take from it in this -- to short -- the argument that we are exposed to very high levels of this daily, so

that this is a big problem in terms of saying that now this little trace amount in a pill is going to change what we're already exposed to at such high levels inherently through routine living.
So that's why, again, we come back to look -- some of the studies where they find associations with cancer is when they take into account endogenous versus exogenous, it's the endogenous part in the calculation that looks like there's the association, not based on the exogenous component in the diet.
BY MR. SLATER:
Q. Coming back to my question, you didn't adopt any of these studies in your opinions and say that's the right model, that's the right way to calculate it, that's the right amount; right?
MR. INSOGNA: Object to form.
BY MR. SLATER:
Q. I'm just making sure I didn't miss it in your report. I didn't see it. I just want to make sure it's not an opinion you drew in your report; that's all.
MR. INSOGNA: Same objection.
A. Other than what you read in the report in

terms of my comments on endogenous and how I just told you how I used that in formulating the opinion, the task at hand, that's it.
BY MR. SLATER:
Q. The studies that talk about endogenous formation and actually try to quantify it -- there's a range of different figures they come up with; right?
A. There is a range.
Q. And would you agree that there's no scientifically accepted consensus as to how to calculate endogenous NDMA?
Would you agree that's still an open question?
A. I think that there is probably room for refining the calculation, but as I'm using it, all of the available calculations have estimated levels far higher than the levels we're talking about here at hand. So --
Q. Did you see -- well, all right. This is, I guess, coming back to my question, though.
You certainly aren't giving the opinion that there's some scientific consensus as to how to calculate endogenous NDMA formation?
There's multiple people that have

different approaches, but there's no scientific consensus on this; right?
A. I would -- I don't know that literature as well as whether or not there's scientific consensus, but I know that there are some studies that even attempted to do analysis through different ways to come up with this and show a range, all, again, very high, much higher than what we're talking about here, and consistent with the overall sort of global picture that the endogenous levels take up the majority of this issue and that a minuscule component is the exogenous component, and so many of these dietary studies that don't take that into account aren't addressing that part -- that confounding issue.
Q. The studies are basing their estimates on mathematical models; right?
A. I believe that they are. Some are measuring directly surrogates of exposure, et cetera, but yes.
Q. For example, you'll acknowledge that certain nitrosamines can be measured and you can figure out to some extent what's coming out of the body, but NDMA, for example, is metabolized and you can't really measure what would be formed in the body; right?

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MR. INSOGNA: Object to form.
A. There are -- I mean, there are the three ways, if I can pull up my --
BY MR. SLATER:
Q. Or do you not know? You can say I don't know and then I move on.
MR. INSOGNA: Object to form.
A. Can I -- I want to point out one area in my report just so that I state it correctly, if I can find it. The Hrudy (ph) study, which is -- okay. Right.
So I was just making sure that I got the three ways in the Hrudy study that were used simultaneously to sort of look at the range that was identified, and so some of them are actually just measuring NDMA levels directly in the blood.
And so if you're quantifying how much, say, for example, you're exogenously taking and you could compare how much is in the blood, you can estimate how much was endogenously created. And so your question of you can't accurately do that -- not necessarily true.
You could estimate the exogenous exposure with the limitations that that has, which are far

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lower, and then evaluate how much is in the blood and deduce that there's endogenous creation, because it's much higher in the blood than what you've estimated that was being taken externally.
BY MR. SLATER:
Q. You're saying that's one potential approach, but you're not giving an opinion to a reasonable degree of scientific certainty that that's the accurate approach; right?
MR. INSOGNA: Object to form.
A. You asked me if it's possible and what's the rationale of it, and it's been done and shows that, yes.
BY MR. SLATER:
Q. But you agree with me you're not reaching an opinion that, for example, the Hrudy model is the right one and the other models are wrong? You're just saying this is one person who came up with this way to do it and you're pointing it out?
Do I understand correctly?
MR. INSOGNA: Object to form.
A. There are multiple ways to do it and I tried to show that there are various ways to do it and that overall the answer is always that it's much higher

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than the exogenous levels in the diet.
BY MR. SLATER:
Q. Did you see any studies that estimated the level of endogenous formation of NDMA at not what you'd consider to be very high levels?
A. There were a range, I think, as we talked about, at various extremes, but even at the lowest levels they were higher -- much higher than, say, the FDA ADI, as an example.
Q. Well, for example, did you see any studies that estimated the level at perhaps 1,000 nanograms a day?
A. I believe that 1,000 nanograms a day, which is about 100 times the 96 nanograms that the FDA has indicated as an acceptable level, so that's my point, is that there are orders of magnitude even at the lowest estimates. That's all I'm saying.
So I think in the end I'd agree with you that I'm not here to opine on what's the appropriate way to do it, but I'm looking at all of the body of literature that's talking about endogenous formation, how to calculate it, and the range -- the lower level of the range is far higher, let alone probably the more likely is about -- the actual true way of doing it is

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above that.
Q. Are you saying that 1,000 nanograms a day of intake of NDMA would be a very high level?
A. No, I'm saying it's a lot higher than 96 nanograms, which was the FDA's accepted daily intake. And this is on routine daily living. That's -- I think that's the point.
Q. Just to come back to my question -- because I got to know how far we have to go and if I have to go start picking up articles in the other room -- you're not offering an opinion that there's a certain level of endogenous formation -- you're saying this is the level that I'm assuming is formed?
You're just telling me there are studies that have measured it with various methods at various levels; correct?
MR. INSOGNA: Object to form.
A. Yes, other than what we've already mentioned in my previous responses.
BY MR. SLATER:
Q. I need to understand this. I didn't see an opinion in your report where you quantified an assumption as to the level of endogenous formation of NDMA in the human body.

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You're not offering a specific opinion as to a specific level; right?
MR. INSOGNA: Object to form.
A. No, other than the ranges that I put in my report.
BY MR. SLATER:
Q. And when you refer to the ranges in your report, you're pointing out that there are different models and different ranges have been presented and that's as far as you're going in terms of quantifying endogenous formation; right?
A. Yes.
Q. And you also hold out the -- for the -- rephrase.
You also agree with me that these models may all be wrong and it may turn out the levels are much lower; right?
MR. INSOGNA: Object to form.
A. There's no evidence about that. We're always happy to evaluate new data. That's how science works. But currently the data suggests that this is the way to do it, that the levels are extremely high.
BY MR. SLATER:
Q. You don't have an opinion as to what the

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level of endogenously-formed NDMA is in the human body?
You don't have an opinion as to a specific level, do you?
MR. INSOGNA: Object to form. Vague.
A. Not other than what I've put in my report that there's a range that's very high compared to the question at hand here and the questions at hand, no.
BY MR. SLATER:
Q. Your opinion is that there's a potential range and that potential range may have some high figures in it, but you're not saying, "In my opinion, this is the right number," because you haven't evaluated that issue or calculated it; right?
A. I'm not saying that it's one number. I'm not saying it's a potential range. It is a clear range that's been reported in the literature of a high -- very high amount and then the low end is still high compared to the levels we're talking about at the FDA level. There is a clear range -- not a potential range. It's a range that we see in the literature.
Q. If a valsartan pill had 1,000 nanograms of NDMA in it -- let me start over.
If a valsartan pill had 1,000 nanograms of NDMA in it, you would agree that's a high exposure;

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right?
MR. INSOGNA: Object to form.
A. That's not what I'm using endogenous amounts for.
BY MR. SLATER:
Q. I'm not asking about endogenous. I'm asking you --
A. I'm telling you -- you're asking if 1,000 nanograms per microgram -- if 1,000 nanograms per day is a high level?
Q. In a pill of valsartan.
MR. INSOGNA: I'm sorry. I missed the question.
BY MR. SLATER:
Q. I'll ask it again. Let me -- we'll start over.
Do you agree that 1,000 nanograms of NDMA in a valsartan pill would be a high exposure?
MR. INSOGNA: I just want to make sure I'm clear. You're saying 1,000 nanograms, is your question?
MR. SLATER: Yes.
A. A high exposure relative to what? Relative to the FDA level that's high --

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BY MR. SLATER:
Q. You just said 1,000 nanograms would even be a high level of NDMA. I'm asking, does that hold true when it's in a pill sold by the people that hired you?
Is it still a high level if it's in the pill from the people that hired you?
MR. INSOGNA: Object to form. Misstates --
BY MR. SLATER:
Q. Or does it now become a low level because they're responsible for it?
MR. INSOGNA: Object to form. Misstates his testimony.
A. I'm trying to tell you that through routine living we have high levels -- 1,000 nanograms is at the lowest estimate of that -- just from living and eating, and that these levels are extremely higher than what the FDA has shown, has reported, or has put out as a threshold of what's safe. That's all I'm saying.
And so what you're asking now, is an extra 1,000 nanograms a lot? No, not in the context of that sea of exposure that we're exposed to all the time just

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from endogenous calculation of that. That's my point.
BY MR. SLATER:
Q. So you're -- well, my question was, is 1,000 nanograms of NDMA in a valsartan pill sold by the manufacturers that hired you a high exposure in and of itself?
MR. INSOGNA: Object to form.
A. No, it is not a high exposure when taking into account how high of exposures we are every day to just routine living, no.
BY MR. SLATER:
Q. So no big deal? Take 1,000 nanograms of NDMA in your pills every day and it's no big deal?
Is that your opinion?
MR. INSOGNA: Object to form. Misstates the testimony.
A. I was asked to -- whether or not that that made any difference, and I think I have opined many times that there's no evidence that it is. Now we're asking about that in relation to the routine daily exposures to this same chemical, and it's trivial in the end compared to what we are all the time, and so the answer is no.
Now, would I take it on purpose? That's a

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different question that's not relevant to what I'm being asked at the moment.
BY MR. SLATER:
Q. Is that not a question -- then that's not the question you were asked to answer here in this case as an expert; right?
A. What? Whether I'd want to take a pill of valsartan? No, nobody asked me that -- to -- my comment on that.
Q. Well, the question of whether or not -- you said it'd be a different question of whether or not -- and when you said would I want to take it, I took that as would a person want to take it or would you want to give that to your patients.
The answer to that would be no; right?
MR. INSOGNA: Object to form. Vague.
BY MR. SLATER:
Q. We went through that yesterday. The answer would be no; right?
A. Yeah. To answer that question, I'd say there's no added benefit of adding that to the pill over what already the benefit is of that pill, so there would be no point in taking it.
Q. All you would be entertaining is potential

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risk; right?
MR. INSOGNA: Object to form.
A. There would be no reason to do that.
BY MR. SLATER:
Q. You'd be adding potential risk and no benefit; correct?
MR. INSOGNA: Object to form.
A. There would be adding no known benefit and we don't have any evidence that it would be adding any risk.
BY MR. SLATER:
Q. You think there's no evidence in the world that that would be adding potential risk?
MR. INSOGNA: Object to form.
A. I think that's the question that we've been asked that we've been talking about, and I think I opined very clearly that there's no evidence to support that hypothesis and changing from the alternative hypothesis -- the alternative hypothesis, no.
BY MR. SLATER:
Q. Isn't really what you're saying is there's evidence, but because of my evaluation of that evidence, I don't believe the evidence is persuasive?
That's really what you're saying; right?

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A. The body of evidence available to us does not allow us to reject the null hypothesis that there's no association with these added trace elements to the alternative hypothesis that there is a clear, not only association, but actual causation of this in terms of cancer. No, there is not enough evidence to make that assertion.
Q. And that's based on your evaluation of the evidence, which you understand other people have looked at and formed different conclusions on the same evidence; right?
MR. INSOGNA: Object to form.
A. I'd have to disagree with that, because I think if I am correct, Dr. Etmenan (ph) didn't even talk about the human epi data, at least that I could see in the report. So maybe they made some conclusion, but they didn't look at even all of the evidence that I think's available to us.
BY MR. SLATER:
Q. If someone didn't look at all the evidence that is available and relevant to the question, that would indicate a flawed methodology; right?
MR. INSOGNA: Object to form.
A. If you're not looking at the most

important elements, which I think, as we've established, are the human epi data, looking at the actual question at hand, then that would be quite problematic if you're coming up with an answer without even taking that into account.

MR. INSOGNA: Adam, are you at a point where we can take a break?

MR. SLATER: Sure. Let's take 10. Off the record.

THE REPORTER: Okay. James?

THE VIDEOGRAPHER: Going off the record.

THE REPORTER: We are going off the record at 1:47 PM.

[A brief recess was taken.]

THE VIDEOGRAPHER: We are back on the record at 2:05 PM.

BY MR. SLATER:

Q. Let's look at Page 44 of your report, please.

This is the page where you talk about animal studies; correct?

A. Yes.

Q. At the bottom of the page, you state, "On the other hand, while animal studies are of limited

utility in extrapolating data to draw firm conclusions about human carcinogenesis, none of the animal studies relied upon by plaintiffs' experts demonstrates that exposure to the levels of NDMA demonstrated to exist in certain valsartan medications would be capable of causing cancer when administered over the brief period that the impurity existed in those medications."

That's what you wrote; right?

A. Yes.

Q. And if I understand correctly, what you're saying is you can't use the animal studies to establish that exposure to the NDMA levels in the actual pills over the actual period of time that they were taken would have been sufficient to cause cancer in the people who are claiming cancer was caused.

Do I understand that correctly?

A. Yes, and the reason for that is because the levels at which -- depending on which study you look at -- but the levels at which they are causing cancers in the animal models are at much, much higher levels than what we're talking about in these trace levels in the valsartan pills.

And so that's what that summary is alluding to.

Q. Coming back to what I asked you, you confirmed yes, that's your opinion in terms of how the animal studies fit into this case; right?

MR. INSOGNA: Object to form.

BY MR. SLATER:

Q. That the animal studies do not prove that the actual exposures in the valsartan pills here over the period of time that these pills were actually taken by people would not cause cancer in humans?

Is -- am I understanding your opinion on the issue of how the animal studies fit in?

MR. INSOGNA: Same objection.

A. At -- yes, at those levels that I'm looking at in those animal studies, they're not supportive of the question at hand.

BY MR. SLATER:

Q. In the animal studies where NDMA was being deliberately given to the animals -- and it was; right? They were deliberately giving it to the animals; right?

A. Yes.

Q. They were giving it deliberately to the animals to cause cancer; right?

A. They were evaluating whether it would cause cancer, yes, and titrating up the levels in

different cohorts, and evaluating at which point were they starting to see cancers, was there a dose relationship, et cetera, and at what level did they start seeing cancers above basal rates in the control group not getting NDMA, which would be a good way to evaluate that question.

Q. NDMA is actually given deliberately to laboratory animals to give them cancer so that they can then be studied once they get diagnosed with cancer; right?

A. Well, now that studies that we were just referring to have established that at certain doses you can elicit a cancer, then the following questions would be okay, now we can use that as models to study cancer, to treat it, to evaluate it, et cetera. Yes, you would have to know the dose at which to elicit it. In other words, if you're underdosing them, they never get the cancer.

And so the answer to your question is yes, though. Now that that was identified, they can use those doses.

Q. When these large doses are given, the intent is to give cancer to these animals and to do it quickly?

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That's the goal; right?
MR. INSOGNA: Object to form.
A. In a model that you're referring to where you're trying to get a cancer so that now you can study the cancer, sure, you'd want to try and elicit the cancer quickly.
BY MR. SLATER:
Q. You rely -- and I think you might have mentioned it, unless I was hearing things -- to certain studies done with monkey animal models; correct?
A. Yes.
Q. And I think that there's two in particular by Adamson.
You're familiar with those studies, you're relying on them; correct?
A. Yes.
Q. And one involved seven monkeys, and the other involved six monkeys.
Does that sound right?
A. Yes.
Q. Are you aware of what Dr. Adamson's view is on the subject of the risk to humans of exposure to NDMA?
MR. INSOGNA: Object to form.

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A. I don't know what his view is, or his opinions.
MR. SLATER: Chris, let's put up the editorial from "The Oncologist," titled "The Finding of N-Nitrosodimethylamine in Common Medicines."
And I think -- are we up to Exhibit is it 16 or 17?
THE REPORTER: I believe it's 16.
MR. SLATER: Hearing nothing to the contrary, I will mark mine as 16.
[Exhibit 16 marked for identification.]
BY MR. SLATER:
Q. Have you seen this editorial authored by Dr. Adamson?
A. I have not.
MR. SLATER: Chris, if we could, could you go to Page 461 of this article, please? And go to the right-hand side of the page, and let's just go to the bottom right paragraphs.
There's a paragraph three from the -- third from the bottom that says, "Aside from their role as complete carcinogens, the nitrosamines are likely to be cofactors or promoters in patients with underlying hepatic damage due to alcoholism, hepatitis, or hepatic

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steatosis."
A. Where is he?
BY MR. SLATER:
Q. Third paragraph from the bottom of the right-hand column.
A. Right. Okay.
Q. Were you aware that Dr. Adamson authored an editorial offering that viewpoint?
A. I wasn't aware of that, but that viewpoint doesn't mean that it's true, if that's your question.
Q. I'm just asking if you're aware that he said that in this editorial.
A. No, I didn't.
Q. Because you've drawn certain conclusions based on his studies on monkeys that you don't believe that we can show that NDMA would increase the risk for cancer to humans, so I thought it might be helpful to show you some -- an editorial that the author of those studies authored last year addressing his viewpoints. I just was curious if you had seen this.
You haven't seen that; right?
A. I hadn't seen that, and when you asked me if I relied on his paper, I relied on the data from his paper, not on his opinions in that paper or here.

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Q. Looking at the bottom right-hand paragraph, it states, "In conclusion, NDMA contamination poses a potential carcinogenic risk of undetermined effect at present for those taking ranitidine, valsartan, or related medications on a regular basis. It is thus incumbent upon industry and the FDA to take steps to identify and eliminate the sources of contamination of medications with this class of carcinogen."
You would agree with that statement; right?
MR. INSOGNA: Object to form.
A. I don't disagree with anything in that statement suggesting that there are possibil -- these are the questions that we're asking now, and we alluded to this in a similar scenario where you asked earlier, that during the time that we're making an evaluation, you want to make an effort to not continue that exposure, but that doesn't confirm that there is a true risk.
All of his words are very carefully chosen. You see "poses a potential risk," that we have to look at this to see if it's actually real. But none of this is saying that this is a definitive problem, et

cetera, et cetera.
So you're right, I don't disagree with that language to say that we have to sort of look into it and evaluate if there's a risk or not. That's what we're doing now, and that's what I did, and found no association.
BY MR. SLATER:
Q. And did you see any articles in your --
MR. SLATER: You can take this down, Chris. I'm through with that article.
BY MR. SLATER:
Q. Did you see any literature that would support the viewpoint that NDMA can cause cancer in monkeys?
A. Cancer in general?
Q. Did you see any published articles in the peer-reviewed literature concluding that NDMA given to monkeys can cause cancer in those monkeys, or other primates, for that matter?
A. NDMA I think in the papers I referenced and saw didn't.
Q. For example, did you see any article in the peer-reviewed literature that concluded that their data supports epidemiology implicating nitrosamines in

causation of cancers of stomach and other organs in alcohol as enhancing internal exposure to nitrosamines?
Did you see any article indicating that?
MR. INSOGNA: Object to form.
A. So you're asking nitrosamines, not NDMA. So that's a different question, and I didn't see that specifically, but I wasn't looking for nitrosamines specifically. I was looking for NDMA.
BY MR. SLATER:
Q. The language I just read to you came from a study regarding NDMA. I'm just letting you know that.
So I'm asking you, did you see a study that studied NDMA with primates or monkeys specifically where it was concluded that the data supported epidemiology implicating nitrosamines in this study they actually studied NDMA and ethanol co-exposure -- I'm sorry. I got to start over. I mixed up sentences.
MR. INSOGNA: Counsel, if you're reading from a document, do you want to put it on the screen so he can follow --
MR. SLATER: No, I don't. I don't.
BY MR. SLATER:
Q. Let me -- Doctor, just to be clear, you're

not aware of a study that utilized NDMA with monkeys and concluded that the data supported epidemiology implicating nitrosamines in causation of cancers of stomach and other organs?
You didn't see any such literature in your review?
MR. INSOGNA: Object to form. If you're going to quote from a document, I believe the witness is entitled to review the document you're quoting from.
MR. SLATER: I'm asking if he saw anything like that in his work to prepare his report and form his opinions. It's a simple question, yes or no.
MR. INSOGNA: Object to form.
MR. SLATER: Counsel, I'm not putting the document up. Please stop interrupting me so I can finish this deposition now.
BY MR. SLATER:
Q. Yes or no? Did you see any such article, Doctor?
A. I didn't see that in my research. I'm always happy to look at new data and analyze it if it comes available.
Q. So in forming your opinions that the -- that studies on monkeys establish the viewpoint that

NDMA would not be causing an increased risk to humans, you didn't take into account any study in which an actual conclusion was able to be drawn that based on a study of monkeys there would be a risk to humans?
You didn't see any such study, you took none into account; correct?
MR. INSOGNA: Object to form.
A. I didn't see that study that you're referring to. I'd be happy to look at it and evaluate its -- how it adds to the body of literature.
BY MR. SLATER:
Q. One of the things we touched on yesterday was documents that were internal to the manufacturers of these contaminated pills.
Remember we talked about that a little bit yesterday?
A. Yes.
Q. If any such documents were authored by people within those companies that, for example, were toxicologists whose job it was to evaluate the risk of this exposure to nitrosamines, you would have wanted to see that; right?
MR. INSOGNA: Object to form. Incomplete hypothetical.

A. More evidence and more data are always important. I relied on the available evidence to me to make an analysis to see about the question at hand here.

So more evidence and more data are always welcome to put into the analysis.

BY MR. SLATER:

Q. Documents showing the opinions and viewpoints of toxicologists who either worked for the manufacturers or were consulted by the manufacturers regarding the risk to humans of the NDMA contamination from your perspective would be certainly something of potential significance that you would have wanted to see; right?

MR. INSOGNA: Object to form.

A. Similar to the opinions of other investigators that you pointed out. I mean, opinions are not data, and I am looking at data to make my own opinion, not rely on someone, what they felt or wrote or said about something. That would not sway my analysis here.

Data, on the other hand, is a different thing.

BY MR. SLATER:

Q. If toxicologists who were familiar with the pills and the NDMA and what it is and the risk who actually worked for these companies evaluated this situation, you certainly would want to see their evaluation; right?

MR. INSOGNA: Object to form. Asked and answered yesterday.

A. And I think just recently I answered of course I would want to see all evidence and data.

BY MR. SLATER:

Q. For example, if a toxicologist who worked for Teva said that NDMA is a potent mutagenetic carcinogen and needs to be controlled at subthreshold of toxicological concern levels, you would want to know that toxicologists working at Teva felt that, and you would want to understand why; right?

MR. INSOGNA: Object to form. Asked and answered. Incomplete hypothetical.

A. I'd want to know all information, how much that would play a role in determining the question I was asked to assess based on available evidence, based on data and investigations, that's -- I don't even know what you're talking about, and you're not telling me the specifics, so it's all vague questionings.

I don't know how that would play a role into my decision here. Would I want to look at it if there was something available? Of course.

BY MR. SLATER:

Q. You'd want to see it, because as you said regarding methodology, if there's something of potential significance, to have a valid methodology you'd need to at least take it into account; right?

MR. INSOGNA: Object to form. Incomplete hypothetical.

A. I don't know what the evidence or data is you're talking about to even say if it was something that should be included in my analysis to begin with.

BY MR. SLATER:

Q. Would the viewpoints of the manufacturers, their internal knowledge of the risk -- and we're talking the companies that actually were selling the pills and were required by law to understand the risks and benefits.

If they had viewpoints on this and had analyzed this situation, that certainly could potentially have been significant to you; right?

MR. INSOGNA: Object to form. Asked and answered.

BY MR. SLATER:

Q. Potentially significant; right? You haven't seen it, so you don't know?

A. I don't --

MR. INSOGNA: Object to form. Asked and answered. Incomplete hypothetical. Also, Adam, I thought at the outset you said you were not going to go into liability questions.

MR. SLATER: This is not a liability question. This has to do with the risk. These questions all go to the evaluation of the risk of the NDMA and NDEA and the pills that were sold.

I'm not talking about avoiding putting the chemical into the pill. That's a different question probably for someone else.

BY MR. SLATER:

Q. So you would want to -- you certainly would want the lawyers who hired you to have given you this type of information that I'm asking you about so you wouldn't have had to sit here right now saying, "I don't know. I haven't seen any of it. Maybe it would matter, maybe it wouldn't. I don't know"?

You'd prefer to have seen it; right?

MR. INSOGNA: Object to form.

A. I don't know how that would have played a role in my analysis, because I don't know what you're talking about.
BY MR. SLATER:
Q. If one of the manufacturers took the position that the NDMA that was found in the valsartan pills presented an unacceptable carcinogenic risk to the intended patient population, you certainly would want to know that; right?
MR. INSOGNA: Same objections.
A. Similar to the previous answer is someone's opinion is different than what the reality is or at least what the data show about that, that specific topic.
So I don't know what you're talking about or the details about it, but if it's just an opinion about somebody, it would not necessarily play a role into the actual data analysis that I'm talking about.
BY MR. SLATER:
Q. What if it was a position taken by the company in a public document that the NDMA in the valsartan that they were selling presented an unacceptable carcinogenic risk to the intended patient population?

MR. INSOGNA: Same objections.
A. That has no data behind it, and I don't know how that would play a role into the data that we've just talked about that's available to me to review.
BY MR. SLATER:
Q. You think that a company would take that position without even having any data available to it?
MR. INSOGNA: Same objections. Incomplete hypothetical. Argumentative.
BY MR. SLATER:
Q. Or you just don't know?
A. I don't know where that position's coming from. Is it because they found these impurities and they think there's a potential risk and they wanted to mitigate it?
I mean, that doesn't tell me that there's a clear association based on data.
Q. You would want to know more? You would want to understand the document? But you certainly would want to have the opportunity to consider that; right?
MR. INSOGNA: Object to form.
A. It sounds like that what you're offering,

though, is opinions and statements, but it's not data that would sway me based on the data that we have available.
So that's all I can say, based on what you're telling me.
BY MR. SLATER:
Q. So the analysis and opinions of, for example, toxicologists who worked for or retained by the defendants to specifically evaluate the risks posed by this NDMA to patients is something you're telling me wouldn't really matter to you?
MR. INSOGNA: Object to form. Incomplete hypothetical.
A. I don't know. I don't know what is involved in this, what you're talking about to even make an opinion on it or state it either way.
BY MR. SLATER:
Q. Coming back to the monkey studies -- rephrase.
Coming back to the animal studies. When the FDA established the acceptable intake limits, it based those limits on studies with rats; correct?
A. Yes.
Q. And I think -- I don't think it's at my

power, but I want to make sure I covered this. We talked yesterday about the long materials considered list, as opposed to the list of numbered references yesterday in your report.
Remember that?
A. Yes.
Q. And I'm going to be transparent. The reason I'm asking you this is so I don't have to walk study by study through this.
I think we established yesterday -- just tell me if I had it right -- if something's on the materials considered list but didn't find its way into the report with a specific reference, it's something that you may have reviewed, may have skimmed it, may have looked at it, but it wasn't so significant that you felt that you needed to actually reference it in the report and rely directly on it; right?
MR. INSOGNA: Object to form.
A. Yes.
BY MR. SLATER:
Q. So I wouldn't need to go through all the studies that weren't cited in the report to ask how it was important to you, because if it was important it would have been in the report; correct?

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MR. INSOGNA: Object to form.
A. I think I mentioned earlier that the references I put in my actual report are token references, representative references on a topic. They're not an exhaustive reference list of every paper that's talked about this topic.
BY MR. SLATER:
Q. Well, that's not my question, and if your answer is that again, we're going to have to go through all the studies, because I'm not going to leave something significant unturned, so let me just make sure you understand where we're coming from.
If there's an article that's listed in the materials considered, but it's not in the report, not specifically referenced, it's not something that you found was so significant to your opinions that you actually specifically referenced it and talked about it; correct?
MR. INSOGNA: Same objection.
A. For the most part, that's probably true. I think I mentioned one of the papers, which is probably getting to what we're getting at now, which was added later, which was talking about how to establish the dose level and acceptable dose levels.

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That one would probably be an important one, because it's a little bit more relevant to the question as hand. But other than that, the majority of them are either accessory and aren't relied upon specifically.
BY MR. SLATER:
Q. If you had seen something in a study that you felt was of significance, you would have talked about it in the report; right?
MR. INSOGNA: Object to form.
A. If I had seen it at the time of the report, yes.
MR. SLATER: Okay. I have no other questions at this time.
MR. INSOGNA: I'm going to have some questions. I don't know about anybody else who's on the line. I'll need a few minutes to organize my notes. So if you want to take maybe 15, and then we can come back.
MR. SLATER: Sure.
MR. INSOGNA: Okay. Let's say 20. Just I don't want you to tell me I'm late again, but I will work as fast as I can.
MR. SLATER: And we're off the record;

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right? Let's go off.
THE VIDEOGRAPHER: We're going off the record at 2:30 PM.
[A brief recess was taken.]
THE VIDEOGRAPHER: We are back on the record at 3:08 PM.
EXAMINATION
BY MR. INSOGNA:
Q. So Dr. Catenacci, I have a few questions for you. I think some other attorneys may have a few questions as well. And this is a little bit awkward, I know, because of the remote nature of this deposition. You're on camera, I'm actually sitting next to you. But if you could just continue to look at the camera, I think that will make it somewhat less awkward, and if we have documents, we'll put those up on screen.
MR. SLATER: Hey, one quick question before you get started, Nick. Wait --
MR. INSOGNA: Yes.
MR. SLATER: I don't see -- I don't see you on here.
A. On video.
MR. SLATER: Your video.
MR. INSOGNA: Oh, you're right. You're

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right. Let me fix that. Let's pause for a second. Let's just go off the record for one second. I dropped my feed.
THE VIDEOGRAPHER: We are going off the record at 3:08 PM.
[A brief recess was taken.]
THE VIDEOGRAPHER: We are back on the record at 3:12 PM.
BY MR. INSOGNA:
Q. So Dr. Catenacci, you were asked a number of questions by plaintiffs' counsel yesterday about the nature of the question you were asked to answer in this case.
Do you recall those?
A. Yes.
Q. Have you in the course of this deposition fully described the question that you were intending to address with your report?
A. Yes, I think that I was able to get across that I was asked to evaluate whether these trace levels of NDMA in valsartan increased or were associated with cancer in people taking them.
And I was able to relay how I went about that, the methodology, and that ultimately after

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evaluating all the evidence, in terms of the starting point of that there is no association, or null hypothesis, that weighing all the evidence, including the body of evidence we discussed, that there was no such association and that the conclusion was that there's not enough evidence to support the allegation that it was increasing the risk of cancer.

Q. And over the course of your work preparing your report in this case, did defendants' counsel attempt to influence your opinions in any way?

A. No.

Q. Were specific opinions suggested to you?

A. No.

Q. But plaintiffs' counsel also asked you about your methodology and questions about whether you did an independent review or looked at what plaintiffs' experts cited and then relied on their documents.

Do you remember those questions?

A. Yes. Yes.

Q. Now, as a scientist, when you answer a question like the question you just described for us a moment ago, what's the starting premise for you?

A. The starting premise, again, in any scientific question if there's a hypothesis, is what's

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the null hypothesis and what's the alternative, and in order to evaluate that from the standpoint where I had the dataset that was being relied upon to suggest that the alternative hypothesis should be accepted, and I looked at that, because that's the evidence being put forth to try and sway against the null hypothesis.

Of course, after evaluating that and looking at that, I looked at the more broader context of all the data available, as we've been discussing, through the routine way that I do research that I've done through my career as a scientist, in terms of all my training and the natural way that one would go about the question like this.

So ultimately I looked at those reports from the plaintiffs' experts that they're relying on very closely, because that's what they were relying on, of course, and pointed out, as I mentioned, the limitations of the argument that's being put forward.

Q. And when you looked for articles beyond what the plaintiffs were relying on, did you find any?

A. Yes.

Q. And how many -- just a ballpark, how many articles would you estimate you considered over the course of your review in this case?

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A. Hundreds.

Q. And can you recall, roughly speaking, how much of that review was a result of your searching?

A. A majority.

Q. Do you feel that the searches you conducted in preparing your report were sufficiently exhaustive to allow you to answer the question as you framed it earlier?

A. Yes.

Q. Are you aware of additional information or data that would change the opinions you've offered in any way?

A. I'm not aware.

Q. Earlier today, plaintiffs' counsel asked whether you made any attempt to calculate an acceptable daily intake of NDMA or NDEA; right?

A. Right.

Q. And I believe that you testified that you did not undertake such an effort; right?

A. Correct.

Q. Was it necessary for you to calculate an ADI of NDMA or of NDEA in order to offer your causation opinion?

A. No.

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Q. And if I recall correctly, plaintiffs' counsel's questions were in the context of some FDA publications that discussed FDA's ADI for NDMA; right?

A. Yes.

Q. Do you know how FDA went about calculating its ADI figure?

A. Yes, I think I had mentioned that a few times through the deposition that it was obtained from the rat data, extrapolating from the rat data using a linear analysis, using very high doses of the agent in that preclinical model, and looking at the time point at which half of the rats got cancer, died, and extrapolating backwards.

Q. And without yourself doing a calculation of an ADI for NDMA or NDEA, were you able to draw any conclusion or form any opinion about the ADI that FDA set forth in his publications?

A. Yeah, it was clearly a low and what I would say conservative estimate, based on I think we talked about just recently all the numbers and levels in the diet and that were endogenous exposures that we're routinely exposed to on a daily basis.

So it just -- it looks obviously low compared to these reports.

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Q. When you say it looks low compared to these reports, can you explain what it is you mean by that?
A. It looks like it's at a very low level compared to the levels that we're talking about and that we saw in many of the dietary studies, just talking about the exogenous exposures that we have, let alone the endogenous exposures that we have through just routine daily living.
And so it seems low compared to what we're routinely exposed to on a daily basis.
Q. And since you mentioned the endogenous exposure, let me ask you a question about that.
Plaintiffs' counsel asked you some questions today about whether you calculated a level of endogenous exposure through the course of preparing your report.
Do you remember those questions?
A. Yes.
Q. Did you do an independent calculation of how much endogenous NDMA people are exposed to on a daily basis?
A. No.
Q. Would doing an independent calculation of

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a level of endogenous NDMA or NDEA have influenced your opinions in this case?
A. No.
Q. When you reviewed the literature that you relied on in your report, did you see calculations that others had done of endogenous levels of NDMA or NDEA?
A. Yes.
Q. And that endogenously formed nitrosamines levels in the studies that you reviewed, how do they compare to exposures from other sources?
A. From other sources like exogenous, do you mean?
Q. Correct. How do the endogenous levels that you saw reported in the medical literature compare to the levels in exogenous sources?
A. They were astronomically higher and dwarf the levels that we have from an exogenous source.
Q. And how, if at all, did that fact inform your opinions?
A. Well, we're looking at, as I mentioned, the levels that we're exposed to on a daily basis. They're extremely high at everyday environmental, including the endogenous exposures.
So that's an important consideration when

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we're talking -- and I was asked about exposures to relatively much smaller levels and potentially for a shorter amount of time in the valsartan products.
Q. Plaintiffs' counsel also asked you a series of questions about the reasonableness of prescribing or taking a valsartan drug containing a nitrosamine impurity versus prescribing or taking one without it.
Do you recall those questions?
A. Yes.
Q. And your testimony as I see it on the record is that there is no reason to take the drug with the impurity because there's no benefit to it.
Do you recall that testimony?
A. Yes.
Q. Can you explain what you mean by there's no benefit to taking the drug with the impurity?
A. I meant that there's no added benefit on top of just taking the drug without the impurity. In other words, there's no benefit from the impurity itself.
In other words, you're still going to get the benefit that you would have gotten -- that it was intended to do, which was an anti-hypertensive

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medication.
Q. So would taking valsartan containing a nitrosamine impurity still offer a benefit to the patient as a sartan drug?
A. Yes.
Q. Is there any evidence of which you're aware that valsartan drugs containing a nitrosamine impurity are any less efficacious for the purpose for which they're prescribed?
A. Not that I'm aware of, no.
Q. Do you hold any opinion or have you seen any literature concerning whether a valsartan drug containing a nitrosamine impurity would still work as intended to control hypertension?
A. I have not seen any evidence to suggest that it wouldn't work the same way that it always would.
Q. Plaintiffs' counsel asked you some questions yesterday about the Pottegard study; right?
A. Yes.
Q. And specifically he asked you whether it's possible that patients in the control arm received valsartan from another manufacturer of the API that was later discovered to have an NDMA or NDEA impurity;

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right?
A. Yes.
Q. Have you seen any evidence in the literature anywhere to suggest that is the case?
A. No.
Q. And so far as you're aware, has the Pottegard study been retracted?
A. No.
Q. Other than plaintiffs' counsel's hypothetical, do you know of any source for such a theory?
A. No.
Q. At the time the Pottegard study was conducted, do you know whether other API manufacturers had announced any discovery of an NDMA or NDEA impurity in their API being sold in Denmark?
A. I don't know.
Q. And you know that the Pottegard study looked at patients in Denmark; correct?
A. Yes.
Q. So at that time, was there any better data available to the authors of the Pottegard study about exposure to valsartan containing an impurity?
A. No.

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Q. So how, if at all, does plaintiffs' counsel's hypothetical about the Pottegard study impact your opinions of the Pottegard study?
A. Not at all.
Q. And I believe you were asked some questions about confounding in the Pottegard study; right?
A. Yes.
Q. And was it your testimony that there is residual confounding in the Pottegard study?
A. Yes, I think that was one of the noted limitations.
Q. And did the potential for residual confounding impact your opinions in any way in this case?
A. No.
Q. In the Pottegard study, was there any incidence of liver cancer in either the control or study arm of the subject?
A. There was not.
Q. Plaintiffs' counsel asked you some questions today about the Gomm study as well; right?
A. Yes.
Q. Specifically asked you about the liver

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cancer finding in that study?
A. Yes.
Q. Do you remember a question about a sentence in your report that said there were not statistically significant associations with cancer overall or any specific answer?
A. Yes.
Q. And plaintiffs' counsel suggested that your report was inaccurate because it did not mention a liver cancer finding in that sentence; correct?
A. That's what he said.
MR. SLATER: Objection. You can answer.
BY MR. INSOGNA:
Q. Do you have your report in front of you?
A. I do.
Q. Look with me, if you would, at Page 39, where you discuss the Gomm study.
A. Yes.
Q. And if you would find that sentence with me where it says, "In other words, taking NDMA containing the valsartan impurity" -- you see that?
A. Yes.
Q. And that was the sentence that plaintiffs' counsel called to your attention; correct?

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A. Yes.
Q. Can you read to me the next sentence in your report?
A. "The analysis of individual cancer types did show a slight statistically significant association but not causation between potentially NDMAs containing valsartan and liver cancer, with the adjusted hazard ratio, but not for any other cancer evaluated in the listed cancers there."
Q. So the sentence immediately after the one that plaintiffs' counsel focused on discussed the liver cancer finding in the Gomm paper?
A. Yes.
MR. SLATER: Objection. You can answer.
BY MR. INSOGNA:
Q. In writing this the way that you did, were you attempting to conceal the liver cancer finding in any way?
MR. SLATER: Objection. You can answer.
A. Obviously not. It's almost like this first sentence should have continued and said other than the analysis of individual cancer types showing the association in liver -- that's probably what I meant and I made an error there and made it into two

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different sentences.
BY MR. INSOGNA:
Q. Turn with me if you would to the discussion of the Hidajat paper, which you have on Page 43 of your report.
Plaintiffs' counsel asked you a number of questions about the Hidajat study today; right?
A. Yes.
Q. He asked you a series of questions about whether the study subjects stayed in the same job title versus in the same job department; right?
A. Yes.
Q. Do you have the Hidajat paper in front of you?
A. Yes.
Q. If you would look with me on Page 251 in the right-hand column under the heading exposure assessment. About three-quarters of the way through that paragraph --
A. Yes.
Q. -- there's a sentence that starts, "Lifetime cumulative exposures."
Do you see that?
A. Yes.

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Q. Can you read that sentence?
A. "Lifetime cumulative exposures to rubber dust, rubber fumes, or N-nitrosamines were calculated for each worker based on the assumed number of years worked and department."
Q. And as you read that sentence -- well, what does that sentence tell you about the way nitrosamine exposures were calculated in the study?
A. They were calculated based on the department of which the worker worked in, and so allowing them with the same job title to move around to different jobs within that department wouldn't affect this analysis.
Q. If you would turn back one page to 250 in Hidajat, please.
A. 250?
Q. Yes, the first page of the study. At the very end of that page, there's a sentence that begins, "Due to," and continues onto the next page.
Do you see that?
MR. SLATER: I'm sorry. I lost where you are. Could you just tell me again, Nick, please?
MR. INSOGNA: Yeah, the very end of Page 250 in Hidajat.

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MR. SLATER: Got it. Thank you.
BY MR. INSOGNA:
Q. Can you read the sentence that begins, "Due to"?
A. "Due to the complexity of exposure patterns and the numerous chemicals used in the rubber production process, disentangling exposure response associations between specific suspected carcinogens and cancer risk in this industry remains difficult."
Q. And did that language inform your opinions about the Hidajat study?
A. Well, it points out what I think I pointed out and other experts have pointed out, is that there's just so much confounding to isolate the contribution of a given toxin or a putative carcinogen is nearly impossible, and they're stating this in that sentence.
Q. And in the Hidajat study they list the carcinogens to which workers are exposed; correct?
A. Yes.
Q. And if you look with me on Page 250 just above where you started reading the paragraph that starts, "Important carcinogenic exposures."
Do you see that?
A. Which paragraph?

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Q. The right-hand column, under the gray table there.
A. What page?
Q. On Page 250, the first page.
A. Oh, the first page. I'm sorry. Okay. Okay. "Important." Yes.
Q. "Important carcinogenic exposures."
A. Uh-huh.
Q. Do you see that list of carcinogens?
A. Yes.
"N-nitrosamines, rubber dust, rubber fumes, polycyclic aromatic hydrocarbons including phthalates, aromatic amines, and beta-naphthylamine, and solvents including benzene, among others."
Q. And when you talk about the potential for confounding and the inability, I believe you read the sentence, to disentangle exposures, are those the other exposures that concerned you with the study?
A. Yes.
Q. Over the course of this deposition, you've been asked a few times about whether you'd like to see certain corporate documents and depositions.
Do you recall those questions?
A. Yes.

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Q. And did you in the course of your review look at any company documents?
A. Yes.
Q. I'd like to look at your reliance list, if we could. And if we could pull that up on the screen.
A. Okay.
Q. I don't know which number this is in the record.
MS. WITTLAKE: (Inaudible) report, which is Exhibit 7. It starts on Page 90.
MR. INSOGNA: Okay. Thank you.
MR. SLATER: I had marked his most recent list of materials considered as Exhibit 11, I think.
MR. INSOGNA: Why don't -- we can put up 11.
MR. SLATER: I'm just letting you know. I thought you were asking. I didn't know if you were asking me. Trying to be helpful.
A. Appreciate it.
MR. SLATER: Anytime. I'm trying to get the last questioner done.
MR. INSOGNA: If you would go to Page 2 of that document, Kate.
MR. SLATER: What page did you say? 18?

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MR. INSOGNA: Page 2 of the document.
MR. SLATER: Oh, Page 2.
BY MR. INSOGNA:
Q. Dr. Catenacci, do you have that in front of you?
If you would turn with me also to Page 2.
A. Yes.
Q. You see there's a heading company documents produced?
A. Yes.
Q. And that continues for a few pages. I want to go through these documents.
But first question, did you review these documents that were provided to you?
A. Yes.
Q. I see the first one listed there is a Teva health hazard assessment re valsartan.
That was a document you had in your possession?
A. Yes.
Q. And did you review it?
A. Yes.
Q. And there are another one, two, three, I see, health hazard assessments there; correct?

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A. Yes.
Q. Did you review each of those documents in preparing your opinions?
A. Yes.
Q. There's also a toxicological assessment of NDMA impurity in valsartan by Dr. Nudelman?
A. Yes.
Q. Did you review that document?
A. Yes.
Q. And I believe plaintiffs' counsel asked you yesterday if you reviewed the deposition of Dr. Nudelman.
Do you recall that?
A. Yes.
Q. And did you review that deposition?
A. I reviewed it. It's been some time since I last looked at it.
Q. And this next document here is a ZHP root cause analysis.
Do you see that?
A. Yes.
Q. Is that a document you reviewed in preparing your opinion?
A. Yes.

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Q. And below that is a Mylan root cause.
Do you see that?
A. Yes.
Q. Is that also a document you reviewed in preparing your opinions?
A. Yes.
Q. And below that is a Teva risk assessment before for valsartan Huahai.
Do you see that?
A. Yes.
Q. Is that a document you reviewed in preparing your opinions?
A. Yes.
Q. And going over the next page, I see another risk assessment and several more tox assessments listed here, as well as some additional data.
You see all these listed?
A. Yes.
Q. Are these all documents that you reviewed in preparing your opinions in this case?
A. Yes.
MR. SLATER: Objection.
BY MR. INSOGNA:

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Q. Now, you --
THE REPORTER: I'm sorry. Sorry. Was the answer yes?
A. Yes.
THE REPORTER: Thank you.
BY MR. INSOGNA:
Q. You did not cite these documents in the body of your report, did you?
A. No.
Q. Did any of these documents influence or alter your independent opinions in any way?
A. No.
Q. And I believe in response to plaintiffs' counsel questions you testified that it would be interesting to see all available evidence.
Was it necessary for you to review corporate depositions in order to form your opinions in this case?
A. No.
Q. Was it necessary for you to review internal corporate documents like these tox assessments that you did review in order to form your opinions in this case?
A. No.

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Q. Why is that?
A. They weren't part of my analysis. They were sort of background information, but they weren't fundamental data points and studies that I relied upon to answer the question that was being asked of me.
Q. In formulating a scientific opinion about causation or whether there's elevated risk, would you rely on what a company said about its own internal risk assessments in formulating those opinions?
A. No.
Q. Would a company's internal risk assessment or testimony dictate how you render causation opinions in a case like this?
A. No, not at all.
Q. One of the things that plaintiffs' counsel focused on in his questioning was the levels of impurity in valsartan tablets.
Do you recall those questions?
A. Yes.
Q. When you -- first of all, in your report, do you identify the levels of putative nitrosamine impurities that you looked at in formulating your opinion?
A. Yes. They're in the table that was from

Page 409

the FDA.
Q. And where did you take that -- you just said you took that data from FDA?
A. Yes.
Q. And why is that the source that you chose to use?
A. This is the publicly-available data that was provided after an extensive analysis of multiple lots and to look at the range and to evaluate that.
Q. And to the extent that there are other potential data points on that question, would those influence your opinions in any way?
A. No. I was looking to see what the levels were, what their ranges were, but really to get a sense of what might be a mean exposure level that a patient might have in a given situation.
Q. Over the course of this two days of deposition now, did any of plaintiffs' counsel's hypotheticals or questions cause you to alter your opinions in any way?
A. No.
MR. INSOGNA: Looking at notes here, Adam. Give me one moment.
MR. SLATER: No. No notes.

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MR. INSOGNA: I'm smiling very widely. I know you're always concerned about that.
Okay. I do not have any more questions for Dr. Catenacci.
MR. KUM: So I do have some questions. So Adam, here's some food for thought. We could argue over this for --
MR. SLATER: I'm not going to --
MR. KUM: -- a couple minutes, but I only have a couple of minutes, and we'd be done.
MR. SLATER: This is what I'll say. If you're telling me a couple minutes, some people's couple minutes is 20, some is two.
MR. KUM: No. No, I'm going to be less than five minutes.
MR. SLATER: Okay. I just want to make it really clear for the record I'm not going to create a big blowup over five minutes of questions. I'm assuming that, Bob, you're the only one who intends to question, that it's not going to be a string of people. So I'm making this concession because it's my understanding only you have to question.
I am reserving all my rights. I'm agreeing to this without prejudice to our position that

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multiple defense lawyers should not question a defense expert. But if it's going to be less than five minutes, I don't think it's worthwhile to create a big battle over it at this point.

Hopefully it will go smoothly and we'll move on, and I'm assuming it will. So -- but I'm reserving all my rights. It's not a concession. I wouldn't want to hear in a conference some day that I agreed to it today and --

MR. KUM: Understood.

MR. SLATER: -- that we waived our rights or anything. I'm just doing it to try to be an easygoing guy today.

MR. KUM: Absolutely cool.

John, are we back on the record? Let me know if we ever went off the record.

THE REPORTER: No -- yeah, we actually didn't go off the record.

MR. KUM: Okay. Well, that's perfect.

EXAMINATION

BY MR. KUM:

Q. Dr. Catenacci, this is Bob Kum. I just have a few follow-ups. I'm going to share my screen with you. Plaintiffs' counsel -- I think he marked

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this I wrote down Exhibit 16.

MR. KUM: Is that correct, John?

THE REPORTER: I can double-check. One moment.

MR. KUM: Well, whatever exhibit this is. We'll just -- I want to --

THE REPORTER: Yes, it is Exhibit 16.

BY MR. KUM:

Q. Doctor, can you see this study?

A. Yes.

Q. And you had indicated you had not seen this prior to today; correct?

A. Yes.

Q. I want to read the first three sentences.

It says, "The causes of cancer are manifold. About one quarter to one third of cancers, depending on the specific tumor and population, are caused by infectious agents, while a smaller fraction can be attributed to genetic predisposition. A larger number, perhaps 50 percent or more, arise from environmental and behavioral causes, such as smoking, alcohol, dietary factors, obesity, and pollution."

What's your reaction to that statement? Do you agree or disagree with that?

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A. I agree with that.

Q. I'm going to scroll a little bit farther down. It's on Page 461.

Do you see the header clinical evidence of carcinogenesis due to contamination of medications? Do you see that?

A. Yes.

Q. In the middle of it -- and I'll just highlight it -- it reads, "A negative association was reported for the incidence of colorectal cancer. Of interest is the absence of mention of an association with HCC, the primary tumor type that was found in preclinical carcinogenicity in multiple species."

Did I read that correctly?

A. Yes.

Q. In layman's terms, what is that -- what is the significance? What does that mean when they talk about the absence of mention of an association of HCC, and how does that relate to your opinions in this case?

A. Well, first, just to point out, HCC means hepatocellular carcinoma, which is liver cancer. And so they're noting that it's of interest that there's no association or mention of this with HCC, which is what preclinical models have suggested.

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So he's pointing it out that it hasn't been demonstrated here in this study.

Q. On the first day, I believe plaintiffs' counsel asked you the generic question of whether you agreed NDMA and NDEA is classified as a probable carcinogen.

Do you remember those questions?

A. Yes.

Q. And I don't believe he followed up with asking you an explanation of what probable carcinogen means as it relates to the IR classification.

Is that correct?

MR. SLATER: Objection.

A. Correct.

BY MR. KUM:

Q. Let me just pull up for you the IARC classification.

So Doctor, you agree that IARC has, in determining whether a chemical or substance is carcinogenic, groups it into different categories; correct?

A. Yes.

Q. And Group 1 here indicates, "The category is used when there is sufficient evidence of

Page 415

carcinogenicity in humans. In other words, there is convincing evidence that the agent causes cancers in humans."

Did I get that correct?

A. Yes, sufficient evidence of carcinogenicity in humans. Yes.

Q. Is NDMA classified as a Group 1 carcinogen?

A. No.

Q. Is NDEA classified as a Group 1 carcinogen?

A. No.

Q. Is it correct that those two substances I've mentioned are classified as Group 2A?

A. Yes.

Q. Let's go to the definition of what 2A is.

Do you see that, Doctor?

A. Yes.

Q. It says here that, "The category is used when there is limited evidence of carcinogenicity in humans and either sufficient evidence of carcinogenicity in experimental animals or strong mechanistic evidence showing that the agent exhibits key characteristics of human carcinogens."

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Did I read that correctly?

A. Yes.

Q. And does that comport with your understanding of what a Group 2A carcinogen is?

A. Yes.

Q. It goes to say that, "Limited evidence of carcinogenicity means that a positive association has been observed between exposure to the agent and cancer, but that other explanations for the observations, technically termed chance, bias, or confounding, could not be ruled out with reasonable confidence."

Did you read that -- did you see that, Doctor?

A. Yes, I see that.

Q. And does that comport with your understanding of why they only considered NDMA or NDEA to have limited evidence of carcinogenicity?

MR. SLATER: Objection. You can answer.

A. Yes.

BY MR. KUM:

Q. Yesterday you also mentioned that -- I believe if -- let me see if I've got my notes correctly -- that IARC does not look at chemicals from a risk perspective.

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Did I get that correct?

MR. SLATER: Objection. You can answer.

A. Yes, I mentioned that yesterday.

BY MR. KUM:

Q. I want to go down here to what IARC says about this.

Do you see there's the header that says, "What does the classification mean in terms of risk?"

Do you see that?

A. Yes.

Q. And it says here that, "The classification indicates the strength of evidence that a cause or agent can cause cancer. The IARC monographs programme seek to identify agents that are cancer hazards, meaning they pose the potential for the exposure to cause cancer. However, the classification does not indicate the level of risk associated with a given level or circumstance of exposure."

Is that what you meant yesterday when you talked about IARC not classifying risks of a chemical?

MR. SLATER: Objection. You can answer.

A. That's exactly what I was referring to.

BY MR. KUM:

Q. Further on, do you see here the header

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that says, "What is the difference between risk and hazard?"

A. Yes.

Q. It says here, "The IARC monographs programmes identifies cancer risks but not does evaluate the risks associated with special levels or circumstances of exposures."

It then goes on to state -- tell me if I'm reading this correctly -- "The distinction between hazard and risk is important. An agent is considered a cancer hazard if it is capable of causing cancer under some circumstances. Risk measures the probability it will occur, taking into account the level of exposure to the agent. The IARC monographs may identify cancer hazards even when risks are very low with known patterns of use or exposure," period.

Again, does that comport with your testimony and the concept you were trying to convey yesterday?

MR. SLATER: Objection.

A. Yes, that's exactly what I was referring to.

MR. KUM: Counsel, thank you very much. I appreciate your accommodation.

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MR. SLATER: No problem. So I assume it's my turn to go back now, based on our back-and-forth? I wasn't saying that pejoratively. Since we -- I think we've agreed no other defense counsel ask questions, I'm going to pick up now.

EXAMINATION

BY MR. SLATER:

Q. Did you -- let me just fix this.

Did you ask the defense if they had any documents that could impact your opinions?

A. I don't think so.

Q. Counsel asked you if the defendants tried to influence you or suggest opinions to you.

Without going into any detail, you've been working with defense counsel for months since March and working with them while you were writing your report and preparing for your deposition; right?

MR. INSOGNA: Object to form.

A. I've been working with them, yes.

BY MR. SLATER:

Q. And you've had multiple meetings with them long before you started preparing for the deposition about what you were being asked to do, and they were providing documents to you, and you said you were going

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back and forth with them pretty regularly; right?

MR. INSOGNA: Object to form.

A. We were discussing papers, usually what my thoughts were about the paper and my opinion.

BY MR. SLATER:

Q. You were asked just by counsel a few moments ago about the Pottegard study, and my paraphrase of what I heard was, "Yes, there's problems with the data, but there's no better data, so that's what we have to work with, basically."

Right?

MR. INSOGNA: Object to form.

A. That's an interesting paraphrase. That's not how I took that. It was more what we've been discussing the whole time, which is all studies have limitations, and there are different levels of evidence that we put different weights on, and that cohort studies like those, even epi data, are by far the highest level of evidence that we have here, albeit with known limitations that we talked about.

BY MR. SLATER:

Q. Well, epidemiologic studies is a category of scientific data; right?

A. Yes.

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Q. Not all epidemiologic studies are equal, right, in terms of their value and their limitations; right?

A. That's I think what I've been saying.

Q. Some -- rephrase.

So when you say human epidemiologic studies have a certain level of value or validity, there are some that actually don't really have much validity or usefulness at all, and there are some that are very valid and useful?

It depends on the specific study, the limitations, and what was being addressed; right?

MR. INSOGNA: Object to form.

A. I think that's what I was relaying throughout the deposition, is that there are different levels of evidence and their weight should be different depending on how strong the study is, how much weight should we put towards it.

BY MR. SLATER:

Q. Do you have your report there?

A. Yes.

Q. Could you go to Page 39, please?

Counsel asked you about some of the language and wording you used in your discussion of the

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Gomm study. I'd like to go down to the bottom of the paragraph about Gomm.

The second-to-last paragraph, you say, "With multiple testing that has been conducted between the two studies, including for each of the various cancers, there is potential that a positive finding here in Gomm et al is due to mere chance, and further analysis is warranted to derive firm conclusions."

Right?

A. Right.

Q. There's also the possibility or potential -- rephrase.

There's also the potential that the positive finding in Gomm is not due to mere chance but actually indicates a real causal association?

That's possible also; right?

MR. INSOGNA: Object to form.

A. A real causal association? Now we're going to -- that's a possibility. Anything's possible, but it's less likely, given all the dataset that we're looking at, and that's why I qualified that this is something that would need to be followed up on in an independent analysis to confirm these findings, especially since other studies haven't shown a liver

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finding, and we just looked at that one article from Adamson, who notes himself it's interesting that there's no association with HCC.

So I think the theme of the argument here from my perspective is that there's no consistency. Yes, there is this one data point, but there are others that are in direct conflict with this, which makes it less likely and more likely random until proven otherwise.

BY MR. SLATER:

Q. You were asked about the company documents --

A. Yes.

Q. -- that are listed on your amended list of materials considered?

A. Yes.

Q. You didn't mention any of them in your report, with the exception of referencing the documents that provided you information about the -- well, let me withdraw that and ask it differently.

The documents are not -- rephrase.

Looking at the company documents produced that counsel just asked you about, you don't discuss those in your report; right?

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A. No.

Q. Meaning I'm correct; right?

A. Yes.

Q. A double negative conundrum.

There was nothing in those doc -- well, rephrase.

Yesterday when I asked you about doctor -- rephrase.

Yesterday when I asked you about Raphael Nudelman's deposition, if my recollection is correct, you didn't even know who Raphael Nudelman was yesterday; right?

A. I had forgotten who he was and what that one was about, because I hadn't read that one in some time, like four months ago. I had read it, but it clearly didn't play a role in my opinion, if that's the question.

Q. The company documents -- well, let me ask you this.

In Raphael Nudelman's deposition, there's nothing that you cited to from that deposition in your report; right?

A. Not specifically.

Q. Do you recall what he said in his deposition at all?

A. I'd have to go back and look at the details.

Q. Do you know who he works for?

A. I know now after reviewing just briefly what it was, was that it was the toxicologist that was evaluating on the side of the defense -- I think Teva.

Q. You just -- you reviewed that today to recollect?

A. I just know that that's what it was. I haven't reviewed the whole deposition since yesterday, no.

Q. Can you tell me anything he said in the deposition at all?

A. I didn't memorize it, no.

Q. Can you tell me anything at all about the deposition? Do you remember anything he said?

MR. INSOGNA: Object to form.

A. I'm happy to look at it and tell you what I thought about it.

BY MR. SLATER:

Q. You don't remember anything from the deposition as you sit here now; right?

A. I'm -- it's been a long time since I

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looked at it.

Q. So I'm correct?

A. That I can't --

Q. You don't recall anything about the deposition as you sit here now; correct?

A. Other than it was a toxicological analysis, that's all I -- no, I don't know the details. I didn't memorize numbers or anything like that.

Q. Go to the company documents produced list that you were asked about. Let's look at the first document, the July 6th, 2018, Teva health hazard assessment regarding valsartan.

What did that assessment conclude; do you recall?

MR. INSOGNA: Object to form.

A. My recollection of these are they're sort of similar to the Fairs (ph) data, in the sense that they're just sort of reporting all adverse events in patients taking the medications by a monthly sort of documentation to follow, if I recall.

BY MR. SLATER:

Q. When did you last look at that document?

A. Oh, it would have been several months ago.

Q. If you had seen anything in any of these

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company documents that was of any significance to you, is it fair to assume you would have discussed that in your report?

A. No. That was not something that I was relying on from an objective standpoint to answer the question that I was asked.

Q. You said just a few minutes ago that it was not necessary for you to see any of the corporate depositions or documents that you weren't shown; but in reality you don't know what's in those documents, so you don't know whether you would want to see them or not, because you don't know what's there; right?

MR. INSOGNA: Object to form.

A. We went through those questions, and I don't know what's in there, so I can't say one way or another. But if -- but I think what we're talking about now you're asking about these other documents I did see -- they didn't really play a role in what I was doing here.

BY MR. SLATER:

Q. What I'm asking is this.

In terms of documents that were not provided to you, there's no way for you to know whether they would have been significant to you or not, because

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you haven't seen them; right?

A. That's fair to say. I don't know what's in them. How can I tell you what I would do?

Q. You were asked about looking at the FDA information regarding the levels of NDMA and NDEA in the pills a few minutes ago; right?

A. Yes.

Q. If in reality the FDA information that you accessed was incomplete in terms of the levels of NDMA and NDEA, and that the levels were actually higher, and the defendants produced to us documents showing higher levels of those substances, you would have wanted to know that so that you could have had the accurate information to rely on and put in your report; right?

MR. INSOGNA: Object to form. Incomplete hypothetical.

A. It would be important to know all data points, as we've established.

BY MR. SLATER:

Q. If I could, I'd like to go to that Oncologist -- you don't have a hard copy of it, right, that editorial from The Oncologist? I think we have to put it up on the screen.

MR. SLATER: Chris, do you think you could

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put that up? I think it's Exhibit 16. And you can go to Page 461, the area that the questioning was on just a few minutes ago. That's great. Thank you.

BY MR. SLATER:

Q. Looking at Page 461 in the right-hand column, you were asked a question about a study that is discussed regarding ranitidine.

Do you see that?

A. Yes.

Q. Have you read that study?

A. I'm not sure what study they're referring to here. All I can see is a number. This is a commentary -- this paper.

Q. It's a study performed at Sloan Kettering regarding ranitidine.

Did you see that study?

A. I don't know. I'd need to see the details of what even the name of the paper is before I could comment.

Q. You were -- rephrase.

Counsel read to you the statement that it was of interest that there was no association mentioned with liver cancer; right?

A. Yes.

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Q. Gomm did find a statistically significant association to liver cancer; correct?

A. We talked about that, yes.

Q. You were shown by counsel some language from the IARC document.

MR. SLATER: You could take that down, Chris. Thanks.

BY MR. SLATER:

Q. You were asked some questions about an IARC document by defense counsel, and it was suggested that IARC did not consider the risk for Group 2A carcinogens, if I understood correctly.

Did I understand correctly the question you were asked?

MR. KUM: Object to form. Misstates testimony.

BY MR. SLATER:

Q. Well, let me ask the question differently.

Do you recall that IARC said that NDMA -- and I'm paraphrasing -- should be considered to be carcinogenic to humans, for all practical purposes?

And the "for all practical purposes" I'm quoting. I know that language was put out by IARC.

Are you familiar that I -- with IARC

saying that?
A. I don't remember seeing that just now, if that's the question with what we were --
Q. No, I don't believe counsel showed that to you just now.
So what I'm asking is, are you aware that IARC with regard to NDMA said that it should be considered carcinogenic to humans, quote, for all practical purposes, close quote?
Are you aware that IARC said that?
THE WITNESS: I'm not aware -- I'm aware of its listing as a 2A carcinogen.
MR. SLATER: I have no other questions.
MR. INSOGNA: I don't have any further --
MR. SLATER: We can get you to your meeting, Doctor. It's time.
MR. INSOGNA: Thank you.
THE VIDEOGRAPHER: We are going off the record at 4:02 PM.

[SIGNATURE RESERVED.]

C E R T I F I C A T E

I, JOHN ARNDT, a Certified Shorthand Reporter and Certified Court Reporter, do hereby certify that prior to the commencement of the examination, DANIEL CATENACCI, M.D., was sworn by me via videoconference to testify the truth, the whole truth and nothing but the truth.
I DO FURTHER CERTIFY that the foregoing is a true and accurate transcript of the proceedings as taken stenographically by and before me at the time, place and on the date hereinbefore set forth.
I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in this action.

_____
JOHN ARNDT, CSR, CCR, RDR, CRR
CSR No. 084-004605
CCR No. 1186

I, DANIEL CATENACCI, M.D., the witness herein, having read the foregoing testimony of the pages of this deposition, do hereby certify it to be a true and correct transcript, subject to the corrections, if any, shown on the attached page.

_____
DANIEL CATENACCI, M.D.

Sworn and subscribed to before me,
This _____ day of _____, 202_.

_____
Notary Public

DEPOSITION ERRATA SHEET

Page No._____Line No._____Change to:_____
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SIGNATURE:_____DATE:_____
DANIEL CATENACCI, M.D.

I, DANIEL CATENACCI, M.D., the witness herein, having read the foregoing testimony of the pages of this deposition, do hereby certify it to be a true and correct transcript, subject to the corrections, if any, shown on the attached page.

Daniel Catenacci

DANIEL CATENACCI, M.D.

Sworn and subscribed to before me,

This 15 day of October, 2021.

Notary Public

BRYAN BLAIR
Notary Public - Arizona
Maricopa County
Commission # 563486
My Comm. Expires April 29, 2023

My notary expires: 04/29/2023

Notarized online using audio-video communication

DEPOSITION ERRATA SHEET

Page No. 23 Line No. 9 Change to: "She's a counsel for Greenberg Traurig"

Reason for change: misspoke

Page No. 26 Line No. _____ Change to: "Kate" - lines 1,5,10,13

Reason for change: misspoke

Page No. 35 Line No. 12 Change to: "for this deposition"

Reason for change: transcription error

Page No. 36 Line No. 6 Change to: Panigrahy

Reason for change: misspelling

Page No. 45 Line No. 13 Change to: "so I have a newer one"

Reason for change: transcription error

Page No. 96 Line No. 7-8 Change to: "nothing I can think of at the moment"

Reason for change: transcription error

SIGNATURE:_____DATE:_____

DANIEL CATENACCI, M.D.

DEPOSITION ERRATA SHEET

Page No. 23 Line No. 19 Change to: Craig Lockhart

Reason for change: transcription error

Page No. 25 Line No. 7 Change to: "I think it was"

Reason for change: transcription error

Page No. 31 Line No. 10 Change to: "up until this"

Reason for change: transcription error

Page No. 52 Line No. 19 Change to: Delete "I'm -- that."

Reason for change: misspoke

Page No. 53 Line No. 6 Change to: "We were just noting data that's out there, that's not definitive, in a section that's talking about risk factors"

Reason for change: comma additions for clarity

Page No. 81 Line No. 7 Change to: "and pointed out"

Reason for change: transcription error

SIGNATURE:_____DATE:_____

DANIEL CATENACCI, M.D.

DEPOSITION ERRATA SHEET

Page No. 98 Line No. 8 Change to: "what I strive to do"

Reason for change: transcription error

Page No. 134 Line No. 22 Change to: "As to what the utility is or is not"

Reason for change: transcription error

Page No. 139 Line No. 21 Change to: "and relay that information"

Reason for change: transcription error

Page No. 148 Line No. 18 Change to: "I think the information is important"

Reason for change: transcription error

Page No. 156 Line No. 19 Change to: "through the portal venous system"

Reason for change: transcription error

Page No. 160 Line No. 15 Change to: "this cancer"

Reason for change: transcription error

SIGNATURE:_____DATE:_____

DANIEL CATENACCI, M.D.

DEPOSITION ERRATA SHEET

Page No. 185 Line No. 22 Change to: "they are standard treatments"

Reason for change: transcription error

Page No. 187 Line No. 2 Change to: "no survival differences"

Reason for change: transcription error

Page No. 188 Line No. 2 Change to: "the risk of discontinuing"

Reason for change: transcription error

Page No. 209 Line No. 11 Change to: "nitrosamines, nitrates, nitrites"

Reason for change: transcription error

Page No. 216 Line No. 6 Change to: "and they note that this limits immortal time bias"

Reason for change: transcription error

Page No. 228 Line No. 6, 20 Change to: Forrest plot

Reason for change: transcription error

SIGNATURE:_____DATE:_____

DANIEL CATENACCI, M.D.

DEPOSITION ERRATA SHEET

Page No. 236 Line No. 4 Change to: "what that means is there"

Reason for change: transcription error

Page No. 252 Line No. 17 Change to: "unlucky to have gotten"

Reason for change: transcription error

Page No._____Line No._____Change to:_____

Reason for change:_____

Page No._____Line No._____Change to:_____

Reason for change:_____

Page No._____Line No._____Change to:_____

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Page No._____Line No._____Change to:_____

Reason for change:_____

SIGNATURE:_____DATE:_____

DANIEL CATENACCI, M.D.

I, DANIEL CATENACCI, M.D., the witness herein, having read the foregoing testimony of the pages of this deposition, do hereby certify it to be a true and correct transcript, subject to the corrections, if any, shown on the attached page.

Daniel Catenacci

DANIEL CATENACCI, M.D.

Sworn and subscribed to before me,

This 15 day of October, 2021.

BRYAN BLAIR
Notary Public - Arizona
Maricopa County
Commission # 563486
My Comm. Expires April 29, 2023

Notary Public

Notarized online using audio-video communication

My notary expires: 04/29/2023

DEPOSITION ERRATA SHEET

Page No. 296 Line No. 11 Change to: "within the exposed group"

Reason for change: transcription error

Page No. 306 Line No. 1 Change to: Peto

Reason for change: misspelling

Page No. 351 Line No. 10 Change to: Hrudey

Reason for change: misspelling

Page No. 362 Line No. 14 Change to: Etminan

Reason for change: misspelling

Page No. 426 Line No. 17 Change to: FAERS data

Reason for change: misspelling

Page No. _____ Line No. _____ Change to: _____

Reason for change: _____

SIGNATURE: _____ DATE: _____

DANIEL CATENACCI, M.D.

DEPOSITION ERRATA SHEET

Page No. 414 Line No. 11 Change to: "the IARC classification"

Reason for change: transcription error

Page No. 313 Line No. 7 Change to: "primary endpoint"

Reason for change: transcription error

Page No. 343 Line No. 21 Change to: "the dietary studies"

Reason for change: transcription error

Page No. 347 Line No. 23 Change to: "in short"

Reason for change: transcription error

Page No. 359 Line No. 19 Change to: "evidence that it does"

Reason for change: transcription error

Page No. 360 Line No. 8 Change to: "me that - to - comment"

Reason for change: transcription error

SIGNATURE:_____DATE:_____

DANIEL CATENACCI, M.D.